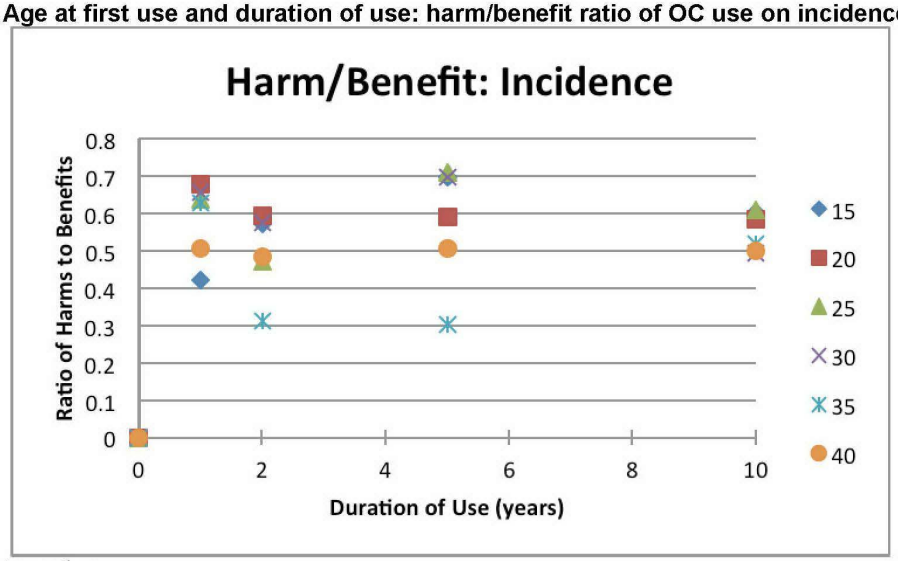
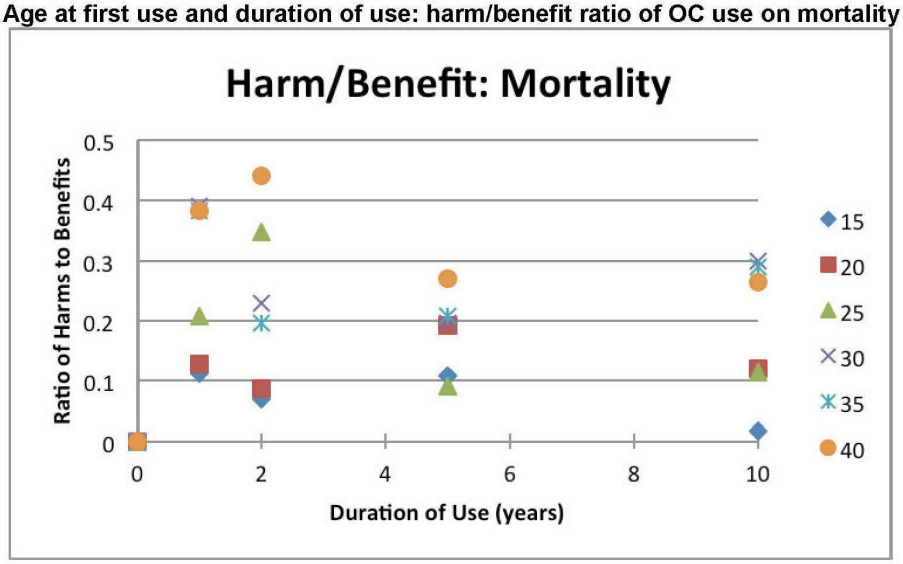
Figure 75. Age at first use and duration of use: harm/benefit ratio of OC use on incidence



OC = oral contraceptive

Figure 76. Age at first use and duration of use: harm/benefit ratio of OC use on mortality



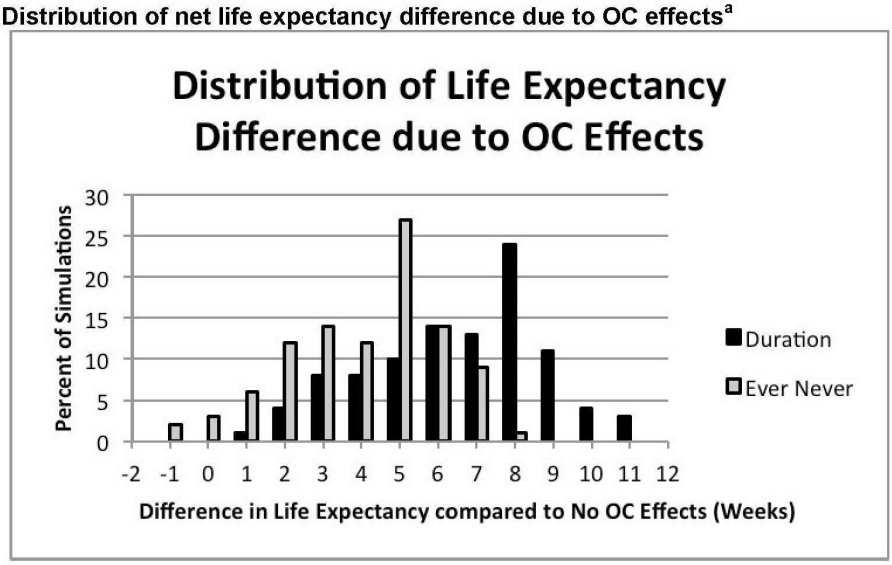
OC = oral contraceptive

Harm/Benefit Acceptability

To assess the impact of uncertainty of the estimates of the relative risks associated with OC use on the tradeoffs between benefits and harms, we ran a series of simulations where the value for each relative risk was drawn from the distributions described in Table 60 (200 draws from these distributions, with 10,000 "subjects" per draw, for a total of 2 million simulations). This method allows us to generate estimates of the effect of uncertainty in the parameter estimates on the uncertainty in the output. For example, Figure 77 compares the distribution of the difference in life expectancy in the general population model between modeling OC effects as ever versus

never, versus dependent on duration of exposure for ovarian cancer and time since last use for breast cancer. Consistent with the results presented earlier, modeling OC effects based on time results in a greater mean gain in life expectancy. The probabilistic analysis shows this clearly, and also shows the distribution of outcomes, including the small proportion of simulations using ever versus never use which results in net loss of life expectancy.

Figure 77. Distribution of net life expectancy difference due to OC effects[a]

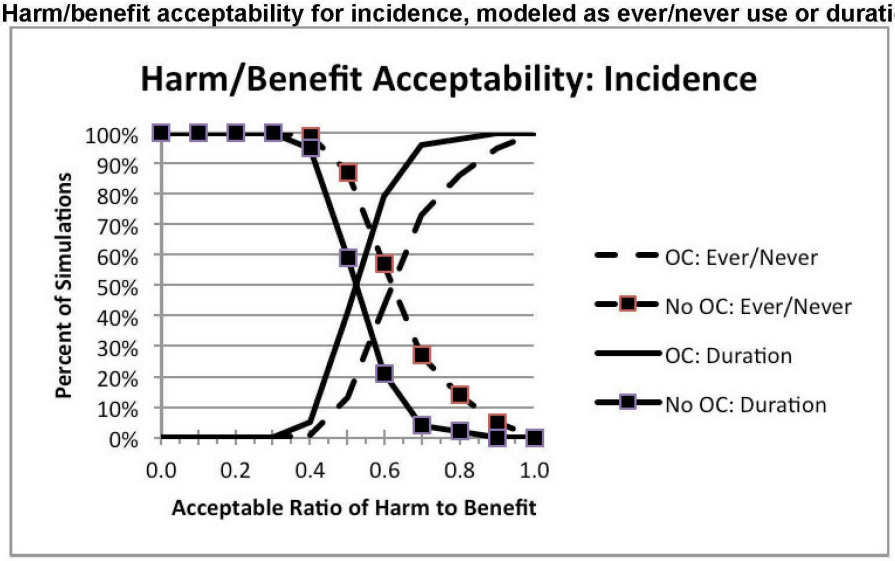


OC = oral contraceptive
[a]Based on OC use in the general population for 100 simulations, where OC effects are either time-dependent for breast and ovarian cancer, or modeled simply as ever versus never.

For the analysis of net benefits, we present the results as acceptability curves—the y-axis represents the proportion of simulations where a given scenario was optimal at a given "willingness-to-pay" (WTP) in terms of harms incurred versus benefits gained; in other words, the sum of all adverse outcomes divided by the sum of all desired outcomes. The point where the lines cross represents the point where half of the simulations favor OC use and half favor nonuse. At a WTP threshold below the point on the x-axis where the lines cross, the majority of simulations favor not using OCs, and, above that point, OC use is favored. The ratio of harms to benefits ranges from 0 (no excess harms) to 1 (harms equal to benefits).

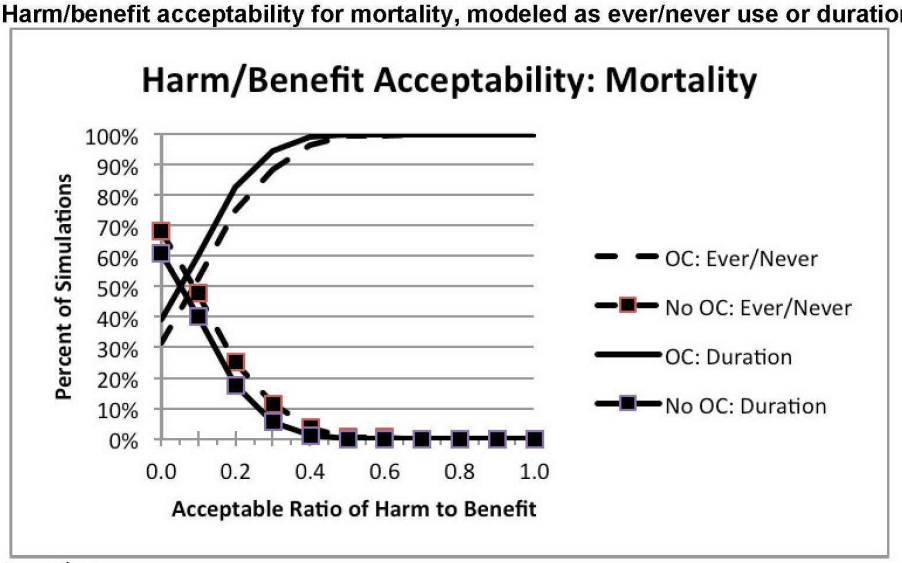
Figures 78 and 79 show the curves for incidence cases and mortality, respectively. The acceptability threshold where OC use is favored is lower for mortality then for incidence, but for both it is below 0.5. For mortality, the model is based on duration of use results in a slightly, more favorable threshold for OC use: the proportion of simulations where a given acceptability threshold was reached was consistently higher because of the higher estimate of ovarian cancers prevented and the lower number of excess breast cancers.

Figure 78. Harm/benefit acceptability for incidence, modeled as ever/never use or duration of use



OC = oral contraceptive

Figure 79. Harm/benefit acceptability for mortality, modeled as ever/never use or duration of use



OC = oral contraceptive

We then explored the relative impact of different components of harm and benefit on acceptability by systematically removing different conditions from the numerator or denominator of the harm/benefit ratio and comparing the proportion of simulations where OC use was favored at a given WTP threshold. For ease of visualization, we present only the proportion of simulations where OC use was acceptable for each combination of harms and benefits at a given WTP threshold; implicitly, the proportion of simulations where OC use was not acceptable at that threshold is 100 percent minus the value for OC use.

In these figures, we sequentially remove groups of harms from the numerator, leaving all benefits, then sequentially remove benefits, leaving all harms. The lines represent the following outcomes:

- Harms (incident cases and mortality)
  - "All combined": breast and cervical cancer, DVT, PE, stroke, MI
  - "No vascular events": breast and cervical cancer only
  - "No cancers": DVT, PE, stroke, MI only
- Benefits (prevented incident cases and deaths)
  - "All combined": ovarian, colorectal, and endometrial cancers
  - "Ovarian and colorectal": ovarian and colorectal cancers only
  - "Ovarian only": ovarian cancer only

Removing vascular events from the harms results in a shift to the left of the acceptability curve for incidence. An even greater shift is seen with removal of breast cancer and cervical cancer (Figure 80). Given the very low absolute increase in cervical cancer incidence associated with OCs, this effect is almost entirely due to breast cancer. This is due to several factors. First, although the relative risk of breast cancer attributable to OC use is relatively small, the absolute number of cases is larger than for vascular events. Second, the degree of uncertainty around the risk estimate for breast cancer is larger than it is for vascular events, with a lower bound very close to 1, so that removing the effect of this uncertainty leads to a greater number of simulations favoring OCs at a given threshold. Conversely, removing colorectal and endometrial cancer resulted in a marked shift of the curve to the right—40 percent of the simulations resulted in a harm/benefit ratio (number of harms incurred per case of ovarian cancer prevented) of 1.0 (Figure 81). This suggests that it is more likely that, for OC use solely for ovarian cancer prevention, the number of harms in terms of incident cases is likely to exceed the benefit (of course, the case might be different if patient preferences for the specific harms and benefits were included). Adding colorectal cancer improved the threshold somewhat, but the major effect was seen by replacing endometrial cancer into the equation. These results are consistent with the tables presented above, where the number needed to prevent one endometrial cancer case is substantially lower than for colorectal or ovarian cancer.

Figure 80. Effect of specific harms on harm/benefit acceptability for incidence (duration model only)

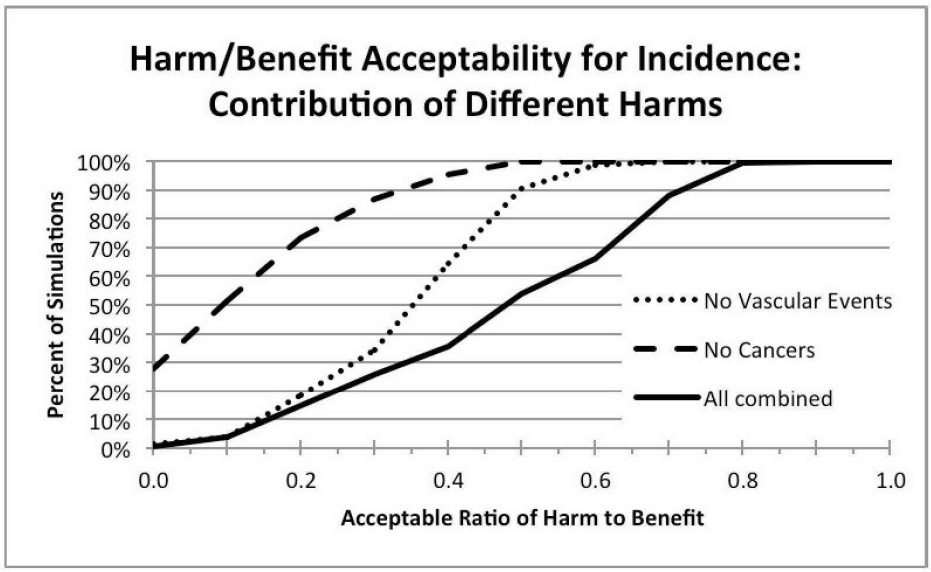
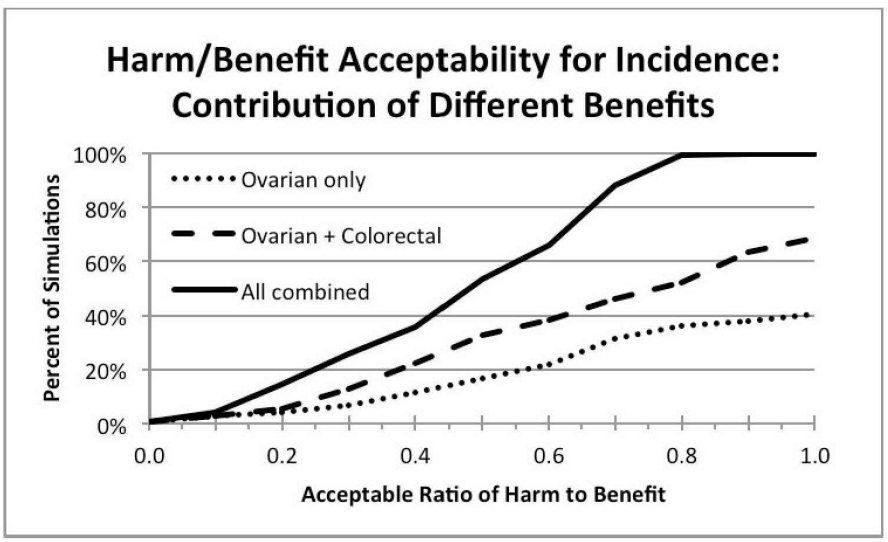


Figure 81. Effect of specific benefits on harm/benefit acceptability for incidence (duration model only)



Results for harms related to mortality were qualitatively similar, but showed an interesting pattern (Figure 82). Removing vascular events actually resulted in decrease in the acceptability threshold at WTO values below 0.1. This is due to the consistent model prediction of increased incidence but decreased mortality from stroke in OC users discussed above: because strokes are included as harms, the net harm in terms of lifetime deaths is smaller when vascular events are included then when they are not. As discussed, these results are due to modeled changes in age-specific incidence leading to changes in age-specific mortality. Taken at face value, these results raise an important point about the limitations of simply counting harms and benefits—clearly,

the potential morbidity from a stroke at a young age is substantial, even if mortality is lower, and this needs to be taken into account by decisionmakers at every level, whether through an informal weighting process or formal methods such as quality-adjusted life expectancy. On the benefit side, the pattern was similar to that seen for incident benefits, although the relative contribution of ovarian cancer alone was much greater (Figure 83).

Figure 82. Effect of specific harms on harm/benefit acceptability for mortality (duration model only)

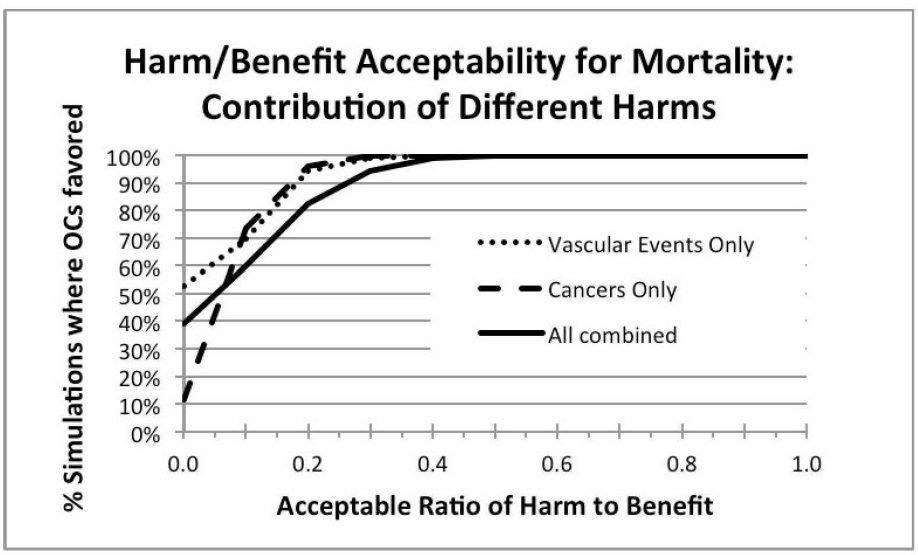
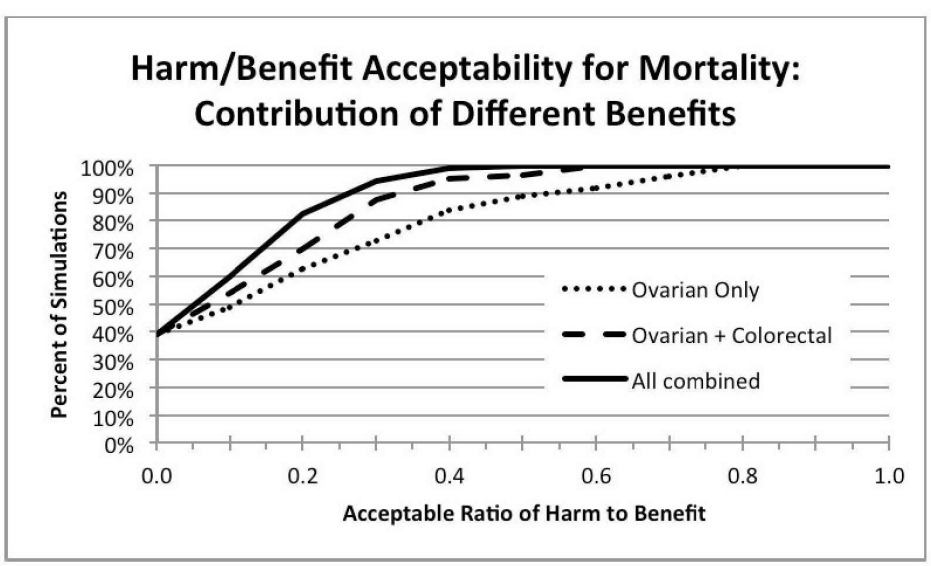


Figure 83. Effect of specific benefits on harm/benefit acceptability for mortality (duration model only)



Discussion

Previous sections of this report have provided discussion of the findings, limitations, and clinical and public health implications of the detailed analyses of OC use and ovarian cancer (Section 2), OC use and other cancers (Section 3), and OC use and vascular events (Section 4). In Section 5, we used mathematical modeling methods to integrate the results of the systematic reviews and meta-analyses of these individual outcomes to better understand the combined effects. In Section 5, we also:

- Summarize the findings of the evidence synthesis
- Compare the results with previous studies
- Discuss the uncertainties, limitations, and subsequent future research needs
- Discuss the clinical and public health implications of the findings, given the uncertainties and limitations

Summary of the Evidence Synthesis

The following are key points from our systematic review and meta-analyses:

- The incidences of ovarian cancer, colorectal cancer, and endometrial cancer were significantly reduced among women who used OCs, with the magnitude of reduction in ovarian cancer risk significantly associated with duration of use (risk declined with longer duration of use, with no evidence of a threshold effect); endometrial cancer risk was also reduced by longer duration of use. The meta-analysis also found a statistically significant effect of time since last use (protective effect decreased as time since last use increased) but not for other characteristics of OC use including ages at use or formulation.
- The reduction in ovarian cancer risk was consistent in different subgroups of women, including BRCA1 and BRCA2 carriers.
- The incidence of breast cancer was significantly increased among women who used OCs, with the magnitude of the increase significantly associated with time since last use (risk decreased with increasing time since last use). The meta-analyses did not find statistically significant effects of other characteristics of OC use including ages at use or formulation.
- The increase in breast cancer risk was consistent in different subgroups of women, including BRCA1 and BRCA2 carriers.
- The incidence of cervical cancer was increased among women who used OCs, although this result was not statistically significant in the meta-analysis.
- The incidences of DVT (including PE) and ischemic stroke were significantly increased among current users of OCs. Risk was associated with increasing estrogen dose, but the meta-analyses did not identify a significant effect of progestin formulation.
- The incidence of MI was increased among women who use OCs, although the results were not statistically significant in the meta-analysis. Again, risk was associated with increasing estrogen dose and, potentially, progestin formulation.
- All of these results are derived from observational studies and may be affected by unmeasured or uncorrected biases.

Modeling Analysis

Key points from our modeling analysis are:

- Using the point estimates for the odds ratios from the meta-analyses (including MI and cervical cancer, where confidence intervals included 1) and adjusting for the age-specific prevalence of OC use, we found the following differences in peak incidence between ever users and never users (for cancers) and current users versus nonusers (for vascular events):
- There was a relatively large absolute increase (maximum increase in annual age-specific incidence 22 per 100,000) in breast cancer risk despite a small relative risk.
- The largest reduction in incidence was in endometrial cancer (maximum decrease in annual age-specific incidence of 55 per 100,000), followed by colorectal cancer (maximum decrease in annual age-specific incidence of 50 per 100,000), and finally ovarian cancer (maximum decrease in annual age-specific incidence of 20 per 100,000), reflecting their relative frequency in women.
- By far the largest absolute increase for any harm was for venous thromboembolism, particularly deep venous thrombosis (maximum increase in annual age-specific incidence of 120 per 100,000); maximum increases in the annual age-specific incidence of PE, stroke, and acute MI were all 30 per 100,000 or less.
- Using a simulation model and these point estimates as well as probabilistic sampling of the age-specific incidence of relevant other events (including hysterectomy, oophorectomy, tubal ligation, and other-cause mortality) to model estimated patterns of OC use in terms of age of starting and duration of use in the general population, we found that:
    - The net effect of OC use on these outcomes was to extend mean life expectancy by approximately 1 month, which is consistent with other cancer prevention strategies in the general population.[376]
    - Modeling the association between OC use and ovarian cancer as a function of duration of use, and between OC use and breast cancer as a function of time since last use, resulted in slightly greater gains in life expectancy compared with modeling these results as a function of ever versus never use, due to a greater reduction in ovarian cancer incidence combined with a lower increase in breast cancer incidence when compared with a model where OC effects were solely based on ever versus never use.
    - Incorporating the joint effects of duration of use and time since last use decreased the population-level effects of OC use on ovarian cancer incidence and overall mortality slightly compared with duration of use alone, but higher than a simple ever/never model.
    - The largest population effect of OC use on incidence of benefits was on colorectal and endometrial cancers rather than ovarian cancers, while reductions in mortality were similar across all three cancers. The largest effect of OC use on both incidence and mortality due to increased risk was seen in breast cancer.
    - For all harms, increases in mortality were much smaller than increases in incidence (and, in some simulations, actually lower with OC use), likely due to a shift in incidence to younger ages, when age-specific mortality from all harms (including cancer) is lower.
    - Assuming a pattern of use similar to the general population, estimated increases in life expectancy were greatest for BRCA1 carriers (approximately 10 months), due to the much higher incidence of ovarian cancer. Estimates for BRCA2 carriers

were approximately equivalent to those for the general population, due to the much larger increase in breast cancer risk relative to the increased ovarian cancer risk.
    - Directly modeling ever versus never use results in larger positive effects of OCs compared with alternative methods to simulate lower exposure to OC use.
- When age at first OC use and duration of use were systematically varied, we found that:
    - Estimates of the effect on life expectancy were positive for durations of use of 2 years or less and positive for women under age 35 for 5 years of use. Longer duration of use led to either lower life expectancy (women 30 and older) or smaller increases in life expectancy for all except women who started at age 15.
    - Estimates for both incidence and mortality for harms (particularly vascular events) were unstable for shorter duration of use across all ages, converging with increasing duration; this is a function of the very low probability of events at younger ages and the assumption of constant risk during use.
    - The total reduction in ovarian, colorectal, and endometrial cancer incidence and mortality was directly related to increased duration, which is largely due to the explicitly modeled association between duration and ovarian cancer incidence.
- Using a probabilistic analysis incorporating the range of uncertainty around the relative risk estimates, we found that:
    - When the association between OC use and ovarian cancer risk was modeled as a function of duration of use, 45 percent of simulations resulted in a life expectancy gain of 1 and 2 months, while 44 percent resulted in gains of 2 to 3 months. When modeled as a function of ever versus never use, 62 percent of gains were between 1 and 2 months, while only 1 percent was greater than 2 months; 2 percent had a net loss of life expectancy of 1 week.
    - For incident harms, breast cancer was the largest contributor. Conversely, for incident benefits, ovarian cancer had almost no effect relative to colorectal and endometrial cancers.
    - For mortality, breast cancer was by far the biggest contributor to uncertainty; removing deaths from vascular events had minimal effect. On the benefit side, the contributions of ovarian, colorectal, and endometrial cancers were roughly equivalent.

Comparison With Previous Modeling Studies

Comparison of the results of the individual meta-analyses with other studies is provided in previous sections of this report. In general, our results were largely consistent with the recent literature, with most of the difference attributable to different inclusion/exclusion criteria.

Our modeling results are roughly consistent with previous U.S.-based studies, which have generally found minimal harms and small-to-moderate net noncontraceptive benefits of OC use—although our overall estimate suggests somewhat larger net benefits, especially in terms of mortality. We briefly describe the main differences in outcomes and approach here.

Fortney et al.[351] used a life table approach to estimate net effects on life expectancy, assuming 5 years of use and varying age at first use from 15 to 44 years of age in 5-year increments, and concluded that there was essentially no net effect, with gains of 4 days for women under age 0, and losses of 18 days for women in their 30s up to 80 days for women over age 45. In contrast, we found an overall net increase of 1 to 2 months across all age groups. The following are possible reasons for this discrepancy:

- The paper by Fortney et al. was published in 1986, so we were able to include subsequently published papers. We also used a more formal set of inclusion/exclusion criteria; the authors excluded a condition if there were less than two papers with a significant association, which eliminated breast cancer for consideration, and used formal meta-analysis methods to synthesize the results.
- Fortney et al. did not include breast or colorectal cancer, DVT, or PE, but did include complications of pregnancy, benign gallbladder disease, pelvic inflammatory disease, and rheumatoid arthritis.
- We used different methods for estimating incidence. Although the baseline estimates presented in Table 1 of the paper are reported as those for women not using OCs, it is unclear from either the table or the paper whether these results were adjusted for the prevalence of OC use or simply the overall rates that were subsequently multiplied by the relative risk estimate. Given the high prevalence of a history of OC use, population-based rates—which are the weighted average of the rates in exposed and unexposed—will be much closer to the rates in ever users compared with never users, all else (such as a history of smoking or an inherited thrombophilia) being equal. Thus, simply multiplying the population rate by the relative risk will overestimate the magnitude of the effect of the exposure in users. We estimated expected incidence based both relative risk and prevalence of exposure.
- We modeled competing risks.
- Fortney et al. applied relative risks derived from incidence to mortality. As shown in our results, the increase in mortality for a given outcome resulting from increased incidence in younger ages attributable to OC use may not result in equivalent increases in mortality because of the effect of age on outcome-specific mortality.

Schlesselman[66] used meta-analytic methods to estimate relative risks related to duration of use and time since last use and applied these estimates using life-table methods and durations of use of 4, 8, and 12 years to estimate the effect of OCs on ovarian, endometrial, cervical, breast, and liver cancers for women 20 to 54 years of age. The estimated mean number of breast and cervical cancers per 100,000 were similar to ours, but the estimates for ovarian and endometrial cancers were significantly lower.

Differences in approach include:

- As with the paper by Fortney et al., we were able to include papers published subsequent to this 1995 analysis. It is also possible that there were differences in inclusion/exclusion criteria and potential differences in the meta-analytic approach, although this is difficult to ascertain from the paper.
- Schlesselman included estimates of duration of use and time since last use effects for all cancers; we included only those which were statistically significant in the meta-analysis (duration for ovarian cancer, time since last use for breast cancer). As seen in our analysis, this had a noticeable effect on outcomes, and, accumulated across multiple cancers, could result in even greater difference.
- We used a different time horizon of 10 to 100 years compared with Schlesselman's 20 to 54 year range. Depending on the size of any effect of time since last use, this could have a substantial effect. This is likely one of the reasons for the similar results for cervical and breast cancers, which have higher incidences when women are in their 40s and 50s compared with ovarian and endometrial cancers.
- We included different nonreproductive cancers. Schlesselman included liver cancer, which is much less common than colorectal cancer; our analysis shows that a protective effect against colorectal cancer would have a marked impact on overall benefits. It is not clear from the paper how competing risks were modeled.

Sonnenberg et al.[350] used a Monte Carlo simulation model to estimate the cost-effectiveness, in dollars per QALY, for a wide range of contraceptive methods. Although the modeling approach is similar to the one we used, the results cannot be directly compared primarily because the results are presented as net effects in terms of QALYs without estimates of individual event rates. The following are other differences:

- Sonnenberg et al. included contraceptive effects, and other contraceptive methods, some of which were assumed to have similar vascular effects as OCs.
- We included papers published subsequent to this 2000 analysis, used different inclusion/exclusion criteria, and used formal meta-analytic methods to derive risk estimates.
- Sonnenberg et al. adjusted for smoking prevalence and the potential interaction between smoking and OC use on relevant outcomes
- They did not include effects on colorectal cancer.
- Data are not provided on the ranges and distributions used in the Monte Carlo simulation.
- The time horizon was very short, only 2 to 5 years, and did not extend past age 50.

Limitations and Uncertainties

The single most important limitation of this analysis is that it is "synthetic"—it is a synthesis of observational data using statistical and mathematical modeling techniques, rather than a directly observed controlled trial designed to minimize potential biases and optimized to detect a clinically significant effect. Women who use OCs are likely to be different from women who never use OCs in a variety of ways that may affect estimates of the association between OCs and a given outcome. For example, concerns about an increased risk for vascular events among obese women may make providers less likely to prescribe oral contraceptives; to the extent that obesity is associated with increased risk for many cancers, this would lead to an overestimation of a protective effect or an underestimation of an increased risk. Although the effect of these differences on the estimate can be mitigated by appropriate study design and analytic methods, they cannot be eliminated.

The majority of evidence we identified was consistent in both direction and magnitude of effect size, showed some evidence of a duration relationship and was adjusted for known confounders. However, this was also the case for hormone replacement therapy as primary prevention for cardiovascular disease. When synthesized into high-quality models, the results strongly suggested a beneficial effect for most women,[377,378] which were subsequently disproven by a randomized trial.[379]

For most women who are considering OCs for contraception, or who have OCs recommended for indications for which there is strong evidence of effectiveness, the lack of RCT data on OCs and potentially fatal outcomes is important, especially if an increased baseline risk of a particular outcome would affect the decision whether or not to use OCs. Given recent evidence on the comparative effectiveness of OCs and long-acting, reversible contraceptives in terms of pregnancy prevention,[380] consideration of the noncontraceptive benefits and harms of OC use relative to other contraceptive methods may become an even greater factor for helping women choose appropriate contraceptive methods. However, quite appropriately, the ultimate decision about using OCs for contraception or as treatment for other conditions should primarily be based on consideration of evidence for their effectiveness for *that indication*, weighed against the potential harms and other relevant attributes (convenience, duration of effectiveness, etc.).

The considerations are somewhat different when the question being considered is whether to recommend OCs primarily to prevent ovarian cancer; here, the potential for bias in the estimates of both benefits and harms also is particularly critical. As noted in the introduction, ovarian cancer has a high mortality rate; there are no effective screening interventions (and, given the biology of the disease, the prospect of effective screening for most women is poor); and surgical removal of the tubes and ovaries carries risks of operative morbidity and the potential effects of early menopause. (We note that the observed reduction in OC risk with tubal ligation is roughly equivalent to that seen with OC use, even with adjustment of OC use among women with tubal ligation—further evaluation of the potential role of tubal ligation as primary prevention for ovarian cancer for women who have completed childbearing is an important area for future research). Approximately 15 percent of women have never used OCs by age 44,[172] and based on the distribution reported in the Nurses' Health Study,[357] another 10 percent of users have taken OCs for less than 12 months. Given the high mortality of ovarian cancer and the lack of proven alternative strategies for prevention that do not involve removal of the ovaries, a course of OCs as primary prevention is potentially a reasonable strategy but one which warrants further research. Even without the potential for biased estimates from the observational studies in the review, the modeling results indicate substantial remaining uncertainty about the balance of harms and benefits of OC use solely for the prevention of ovarian cancer.

Despite the desirability of an unbiased estimate of risk, a formal prospective trial would face numerous, perhaps insurmountable, challenges, as described below.

Sample size and duration of followup, particularly if ovarian cancer is the primary outcome. For example, in a trial targeting women aged 35 to 39 for prevention of ovarian cancer incidence, the expected incidence ovarian cancer by age 55 would be 0.2 percent; assuming a 70-percent reduction in incidence, a trial would require 20 years of followup of over 70,000 subjects *per arm* using an alpha of 0.05 and a beta of 0.2. For mortality to be the endpoint, the trial would need to be extended an additional 5 years. Even if endometrial and colorectal cancer were added as trial outcomes, sample sizes would be over 5,000 per arm for a 20-year study to detect differences in incidence and 25,000 for a 25-year study to detect differences in mortality. None

of these estimates includes correction for loss to followup or hysterectomy or oophorectomy for other causes.

Although alternative statistical analyses or composite outcomes might reduce sample size somewhat, a trial of OCs versus placebo or another method would still require, at the very least, a similar sample size to the Women's Health Initiative with at least twice the length of followup. Maintaining followup in a study of that size for that duration would be challenging, to say the least. Another issue with a study of such long duration would be the inherent problem of applicability: by the time the study was done, alternative methods of contraception (including OC formulations) may well be available and preferred to the formulations tested in the trial.

Recruitment and inclusion/exclusion criteria. In addition to the normal difficulties of recruitment, a substantial proportion of women who are either never users of OCs or used OCs for less than 12 months would be women who had medical contraindications, religious or other objections to OC use, or who stopped OC use because of side effects. Recruitment is always an issue for any randomized trial; one that uses a daily oral medication with known side effects and potential serious short- and long-term harms for primary prevention of a relatively rare cancer would face more difficulty than usual.

Choice of comparator. For reproductive-age women not using another contraceptive method, placebo alone would not be acceptable, further complicating trial logistics if women in both arms would be required to use an alternative contraceptive method. If some of those methods are also effective against ovarian cancer, or increase risk of vascular events, sample size would need to be increased even more. Given the recognizable effects of OCs on menstrual symptoms, blinding would be difficult.

Safety monitoring. The Women's Health Initiative used a complex composite endpoint that included both benefits and harms; a trial of OCs for primary prevention of ovarian cancer would likely require a similar design. However, establishing appropriate safety monitoring, particularly rules for stopping, would be even more complex since the majority of the vascular harms would occur during treatment, while benefits would not be seen for 15 to 25 years.

These daunting challenges create a dilemma. Ovarian cancer is a disease with high mortality where both the disease itself and the treatments have a profound negative impact on quality-of-life in the time between diagnosis and death—and there are no effective preventive strategies. On one hand, the current evidence, while highly suggestive, has inherent limitations that may be leading to incorrect estimates of OC effectiveness. Even ignoring those limitations, there is a high degree of remaining uncertainty about harm/benefit tradeoffs. Future research to fill in the evidence gaps discussed below should improve the ability of researchers to synthesize the available evidence from observational studies, but ultimately the inherent biases associated with observational studies means that some uncertainty will remain even if all the evidence gaps related to observational studies are filled. On the other hand, a definitive trial to address the question would be, in the best-case scenario, hugely expensive and complex. One option might be a trial in a high-risk population, such as BRCA1 and BRCA 2 carriers, where higher incidence rates would substantially reduce sample size. However, there are different challenges with a study in this population, particularly the choice of appropriate comparator; given the known high risk of these conditions and the availability of other treatment options, a placebo-controlled study might face substantial recruitment challenges, and, without a placebo group, it would be very difficult to draw any inferences about the potential applicability of results in BRCA carriers to the general population.

One important next step in developing a research agenda is to formally identify the situations where a decision to start or continue OCs would be done primarily for the purpose of preventing ovarian cancer (and potentially other cancers) and assess how much certainty would be required to make a recommendation for or against this use. One potential future application of the microsimulation model developed for this review is to address some of these issues quantitatively, to help determine the ultimate feasibility of a definitive trial. A first step might be to apply value-of-information analysis to further quantitate the relative contribution of the uncertainties about the tradeoffs between harms and benefits and evaluate the efficiency of potential study designs and sample sizes.[381-383]

Model Limitations and Evidence Gaps

The limitations of the model and its results can be divided into limitations of the model *structure*—the type of model, the methods for converting the available literature into probabilities that the model can use, the assumptions about the relationship between different parameters, the methods for analysis—and of the model *parameters*, which derive from the availability and quality of the data. Because both of these types of limitations are ultimately driven by the data, we discuss how future research can address these limitations in each section.

Model Structure Limitations

Design

We used a semi-Markov state-transition model, which reflects current practice. Instead of running the model as a cohort analysis, where the model provided estimates of the probability of the events of interest based on the parameter values, we ran the model as a microsimulation, where multiple simulations of a series of "individual" subjects with characteristics drawn from appropriate distributions are performed. The main advantage of this approach is that the conditional probability of a transition from one state to another can be conditioned on the underlying state, the time spent in the simulation, and events in past states in a tractable model structure. The main disadvantage is the computational time required to perform the simulations. Some of this time may be due to the specific software package used, which we chose primarily for its ease of programming; using an alternative program would increase the efficiency of calculations, but would be more difficult to program. Because of the computational time required for some of the analyses, we limited the number of "subjects" for a particular analysis (for example, 5000 per each age at first use and duration of use combination). This resulted in unstable results, especially for rare events. However, even this limitation is helpful, since it reinforces the importance of adequate sample size in achieving stable estimates of rare events, which certainly fits the description of vascular events in young women. More iterations would narrow the confidence intervals for the model-based estimates further—but it is worth considering that if the effect size is small enough to require a very large number of simulations, the individual clinical risk, and public health impact, is likely to be relatively small.

Independence of Risks

We assumed that the risk estimates obtained from the meta-analyses, most of which were derived from individual studies with multivariate analyses, were independent of each other—in other words, the estimate for the relative risk for ovarian cancer associated with OC use was independent of any other patient characteristics, such as parity. However, this may not be the case. This may be particularly important for hysterectomy, which is a competing risk for ovarian,

cervical, and endometrial cancer, and which may be affected by OC use. We also modeled individual cancer risks independently, but this is clearly not the case, for both familial cancer syndromes and sporadic cancers, which may share risk factors. Ideally, the model would be run using parameter estimates that incorporated correlations where appropriate.

The model-predicted lifetime incidence for cancers, adjusted for population-level estimates of OC use and relative risks estimated from the meta-analyses, closely approximates estimates based directly on age-specific incidence (Appendix F), which provides some reassurance that the assumption of independence is not resulting in substantial bias.

Other States and Other Contraceptive Methods

We originally included other relevant health states, including menarche and pregnancy, and the range of other contraceptive methods with their effectiveness against pregnancy. For the purposes of this analysis, we excluded these states and other methods for several reasons. First, there is a lack of data on the dynamics of contraceptive method switching; because the majority of the data on OC use and the outcomes of interest was based on comparisons between OC users and all other methods combined, the assumptions and extra work required to derive reasonable estimates would not have added any extra reliability or precision to our analysis.

Second, during early model runs, it became apparent that pregnancy was also a potential competing risk, one which had different probabilities based on age and contraceptive method. Because parity was almost universally adjusted for in the studies included in the meta-analyses, we elected to eliminate pregnancy as a state. However, for a more comprehensive analysis of the combined harms and benefits of OCs, adding pregnancy (including pregnancy-specific vascular event rates) is an important next step. Including other reproductive states, such as menarche and lactation, would also allow modeling the effect of reduction in ovulation, rather than OC use alone, as a modifier of ovarian cancer risk. However, incorporating these into the model will be facilitated by more standardized reporting, as discussed further below.

Finally, the model, which estimates mortality based on age- and race-specific survival after detection of an incidence case, consistently underestimates lifetime mortality risk compared with estimates derived from death certificate data. This is consistent with other "incidence-based mortality" models, where overall mortality estimates are derived from specific survival functions based on patient or tumor characteristics.[384,385] There are multiple explanations for this, including (1) the effect of competing risks for other cause mortality within the model after diagnosis, (2) age/period/cohort effects in the death certificate data that are not reflected in the model estimates, (3) the fact that SEER incidence and survival data represent a sample of the population, while the mortality data are derived from the entire population, and (4) inadequate modeling of mortality more than 5 years after survival (particularly for breast cancer). Since the potential underestimation of cancer mortality affects both potential harms of OC use (breast and cervical cancer) and benefits (ovarian, endometrial, and colorectal), the net effect on the overall balance of mortality harm and benefit is likely to be small but is clearly worthy of further exploration.

Other Potential Confounders and Effect Modifiers

We did not model the potential effect of other characteristics, particularly smoking and obesity, which could plausibly affect contraceptive method choice, risk of different cancers or vascular events, or the association between OC use and these outcomes. The potential impact of smoking status and obesity on estimated risks, both at the individual patient level and at the population level, should be incorporated in future modeling studies.

Ever Versus Never Exposure Versus Time-Dependent Effects

Although the qualitative results were similar whether ovarian and breast cancer risks were modeled as ever/never exposure versus time dependent, the time-dependent approach resulted in better outcomes (greater life expectancy, lower threshold for acceptable harm/benefit ratios), suggesting that how exposure is modeled (and, implicitly, how exposure is measured in studies) could have a more substantial impact on model predictions if it held for additional outcomes. Conversely, because the increased risk of vascular events during current OC use was assumed to be constant over time, longer duration of OC use resulted in greater risk of a vascular event. If, as some of the studies reviewed suggest, risk is highest in early use, then this assumption overestimates the harms associated with longer duration.

Model Structure Evidence Gaps

The following are key future research needs for a model structure:

- Needed are better estimates of correlations between parameters; for example, using the covariate estimates from logistic regression models derived from pooled analyses for all relevant variables instead of the adjusted odds ratios. This would require publication (perhaps in an online appendix), or access to, the actual models used rather than the summary odds ratios and confidence limits typically reported.
- One advantage of microsimulation is that it can generate simulated data sets of individuals, with characteristics such as age of events, history of past events, and so on. These data sets could be used to explore some of these issues related to correlation as well as issues related to study design, sample size, etc. For example, one could simulate a large number of individuals using a fixed estimate of relative risk, then sample the data set using different study designs and sample sizes to identify any systematic effects on bias or precision.
- Incorporate additional reproductive history into models; again, use of simulated data sets could be helpful in exploring the relationship between ovulatory cycles, OC use, and ovarian cancer risk.
- To the extent possible, observational studies should report associations as functions both of ever versus never, or current versus noncurrent use, and duration of use. Pooled analyses, such as those of the Collaborative Group on Epidemiological Studies of Ovarian Cancer,[21] are an excellent way to address some of these limitations. Although access to the raw data is extremely useful, the ability to overcome inconsistencies in reporting is ultimately dependent on how consistently the data was collected. As noted below, some standardization of how duration of use and other potentially relevant parameters are both recorded and reported would also be extremely helpful.

Model Parameter Limitations

Data Reporting/Quality

Data limitations for specific outcomes are noted in the individual sections, but there are general issues that apply to most of the data, particularly for the risk data.

Imprecision and bias. Using a stochastic modeling approach—where data values are drawn from appropriate distributions describing the data—is one way to incorporate the effects of imprecision in estimates resulting from small studies, particularly for rare events, since the effects of the imprecision in the input values are reflected in the distribution of output values. However, even the most precise estimates are not helpful if they are biased in some way;

although models can potentially be used to evaluate a possible effect of bias, and to potentially correct for it, there are no clear standards for this.

Data structure. One limitation common to many simulations where age is an important factor affecting probabilities is that available data on age-specific event probabilities are cross-sectional and may represent cohort effects that are not captured in the model. As the figures in Section 1 show, there is some suggestion of a cohort effect in ovarian cancer incidence due to increasing use of OCs; if this is the case, then the reduction in risk predicted by any model that uses these data to generate age-specific probabilities will overestimate the impact of OC use in the future. Some of this effect may also be seen even with harms from vascular events—for example, age-specific probabilities may decrease with time, as awareness of the possibility of complications leads to more selective use of OCs, or increase with time, especially for less severe cases, where a higher index of suspicion on the part of clinicians would lead to a lower threshold for testing to make a definitive diagnosis.

Inconsistency in reporting. As noted in the individual sections, there was wide disparity in how various potential confounders or effect modifiers, such as parity, duration of OC use, time since last use, woman's age, etc., were described in published papers. While we recognize that the needs of specific studies or the idiosyncrasies of particular data sets may require different categorization of relevant parameters during analysis, it would be extremely helpful for meta-analysis and simulation modeling if there were reporting standards that allowed consistent comparison across studies, which could be presented as an alternate to the categorization selected for the main analysis. Again, this could be presented online.

Data Choices and Available Data

There were minimal data available for some important potential parameters. For others, available data sources may have inherent biases that affect the model.

Data Sources. We used hospitalization rates, and in-hospital mortality, to derive age-specific probabilities of vascular events. To the extent that these outcomes, in particular DVT, may be managed on an outpatient basis, this will underestimate the rates. Similarly, hysterectomy is increasingly being performed in outpatient settings, and hospital-based data may underestimate true population rates. Use of in-hospital mortality may underestimate longer term mortality due to vascular events, although, to the extent the risk of recurrence is reduced by stopping pills, long-term mortality after OC-associated vascular events may be lower than after events associated with other causes. For cancers, we assumed cure after 5 years and did not incorporate the risk of longer term recurrence, which may underestimate total mortality, particularly for breast cancer.

Utilities/Preferences. Quality-adjusted life expectancy is a generally well-accepted method among health policy researchers for integrating the effects of interventions on both quality-of-life and life expectancy. Although estimates for utilities for all of the relevant outcomes were available, we did not identify any utilities for the use of OCs. The studies that incorporated QALYs in their analyses implicitly assumed that OC use has a utility of 1.0; given that a substantial proportion of women who start OCs discontinue due to side effects, this is clearly not the case.

On the other hand, many women may have improvement in quality of life because of OC effects on menstrual symptoms. Some estimate of the effect of OC use on quality of life in the context of use for prevention purposes is needed. Although groups making recommendations typically focus on a semiquantitative assessment of harms versus benefits with some consideration of quality of life, appropriately capturing patient preferences is especially

important for primary prevention. Our acceptability analysis shows that the different harms and benefits contribute differently to incidence (where quality of life is a major factor) compared with mortality. Given that vascular events contribute much more to incidence than mortality (because of the lower age-specific mortality), the potential impact of long-term morbidity from stroke and MI, in particular, should ultimately be considered.

Another factor that needs to be incorporated in any preference/quality-of-life study is time preference. In the setting of OCs for primary prevention of cancer, the benefits occur much later in the future than the potential risks. Deriving empirically-driven discount rates is an important component of future research.

Progestin-only pills. Because the risk of vascular events appears to primarily be related to the estrogen component of combined OCs (Section 4), and because there is evidence from both basic science[170] and observational studies (Section 2) that the progestational component of OCs is the primary factor affecting reduction in ovarian cancer risk, use of progestin-only pills as the OC of choice for reducing OC risk seems attractive. However, largely because there is little use of progestin-only pills, there is a paucity of evidence regarding their effects, particularly on long-term outcomes.

Other patterns of use. Although there is no biological reason to suspect that continuous OC use (i.e., no week without pills to allow menses) would have differential effects on any of these outcomes, data to confirm this would be useful. In addition, more data on both the frequency of use and the outcomes of use for OCs in women over 45 would be extremely helpful.

Model Parameters Evidence Gaps

The following evidence gaps for model parameters should be addressed:

- Consensus among researchers and editors on standardized reporting of key variables would be extremely helpful. One approach would be through the development of consensus data collection and reporting standards under the sponsorship of one or more organizations with an interest in the area, such as the American Cancer Society, NIH, WHO, etc.
- More precise estimates of longer term outcomes are needed.
- Patient preferences for relevant outcomes, as well as for the use of OCs, need to be incorporated into models used for estimating the outcomes of OC use. Ideally, these would include both utilities derived from standard methods of utility elicitation, as well as by methods such as conjoint analysis which allow elicitation of preferences for multiple attributes.[386]
- More data are needed on the potential effects of progestin-only pills on long-term outcomes. However, given our findings that vascular events make a minimal contribution to the harm/benefit ratio in terms of mortality, the value of further research into the potential of progestin-only pills for primary prevention should be assessed first. This could be facilitated by better data on the long-term quality-of-life impact of vascular events in young women.

Potential Next Steps

Although we did not perform a formal value-of-information analysis, the results of our evidence synthesis and modeling do suggest that addressing certain research needs first would have a greater impact in reducing uncertainty about the relative harms and benefits of OCs for

primary prevention of ovarian cancer. Within the context of specific issues discussed above, we would suggest the following broad areas be given priority.

Assessing patient preferences, including those related to regular use of OCs for noncontraceptive purposes. Given the finding that vascular events contribute little to uncertainty about the harm/benefit ratio in terms of mortality, a better understanding of how long-term morbidity associated with these events in younger women, would be extremely helpful. This research area also has the advantage of requiring considerably fewer resources than, for example, a 20-year randomized trial of more than 140,000 subjects.

Achieving greater certainty about the importance of time-related effects relative to ever-never exposure. This could be facilitated by consensus on reporting standards. In terms of cancers, we would suggest prioritizing colorectal cancer and breast cancer because (a) there is greater certainty regarding the time-dependent effects of ovarian cancer, (b) although endometrial cancer is an important contributor to the mortality harm/benefit ratio, there is less uncertainty about the benefits of OC use, and (c) increased cervical cancer risk has almost no contribution to the overall mortality risk (note that this is not likely to be true in settings where adequate screening, or widespread population coverage with vaccination against oncogenic human papillomavirus, is unavailable). In terms of vascular events, the most important uncertainty is the extent to which risk may or may not decrease with increasing duration of use.

Another need is for better understanding of the potential effects of OC formulation on breast and colorectal cancer risks. Again, these two contribute substantially to the harm/benefit ratio in terms of mortality. Particularly in the context of the potential use of progestin-only pills, greater certainty about the potential effects relative to combination OCs on these two cancers would be particularly helpful.

Clinical and Public Health Implications of the Findings

The overall strength of evidence for the literature review was moderate to low with applicability for current practice affected by two major factors. First, there was a large number of studies (many of higher quality) performed outside of the United States, where several differences may affect observed associations—differences in available OC formulations; in population patterns of contraceptive use; in genetic factors (e.g., inherited thrombophilias) and acquired factors (e.g., prevalence of smoking) that interact with OC effects; and in health system attributes, particularly regarding population coverage for screen-detectable cancers. Second, particularly for cancers, the long period between exposure to OCs and development of the cancer means that much of the available literature is based on exposure to OC formulations that are no longer on the market—which has implications for both harms and benefits.

Although there are published guidelines for assessing the quality of modeling studies,[387] there is no consensus on how to consider the "strength of evidence" of the results of modeling studies. In most cases, modeling is done because randomized trials are not available and, even in the best-case scenario, will be based on evidence from lesser quality studies. Given the inherent limitations of modeling, many of which are discussed above and in Appendix F, the strength of evidence for even the most sophisticated model will be at best moderate and, realistically, low in most cases. That is certainly the case with these results, which are based on low-moderate quality evidence for the most important parameters of interest.

With these caveats, based on our synthesis of the best available literature, the clinical and public health implications of our review include the following:

- Assuming that the general estimates of increased or decreased risk are not overly biased by observational studies, the net effects on cancers and vascular events of current patterns of OC use in the general population likely result in a net increase in life expectancy of 1-2 months, which is comparable to many other preventive interventions.[376] This is in addition to any effects from prevention of unwanted pregnancy. In our probabilistic analysis, OC use resulted in net loss in life expectancy in less than 5 percent of simulations.
- The model predicts similar net gains in BRCA1 and BRCA2 carriers; in BRCA1 carriers, who have marked elevation in ovarian cancer risk, the gain may be as high as 10 months.
- These results should be reassuring to women who are considering OC use for contraceptive purposes or who are prescribed OCs for treatment of other conditions.
- Other than for ovarian cancer, the effects of increasing duration of use for individual outcomes is unclear. The modeling results suggest that the net benefits of OC use decrease between 5 years of use (the approximate mean duration of use in the population) when they are generally positive, especially at younger ages, and 10 years of use for all but the youngest women. This may be a function of a conservative assumption about constant risk over time for exposed women, but based on the available data, there is less confidence in the net benefits of duration of use longer than 5 years for women at average risk of ovarian cancer. For a woman who has used OCs for 5 years and is considering other contraceptive methods, there is insufficient evidence to suggest continuing to use OCs solely for their effect on ovarian cancer risk—particularly since there is consistent evidence that at least one other method (tubal sterilization) reduces risk by a similar order of magnitude and recent evidence that other nonpermanent methods may also reduce risk.[123]
- For a woman who has never used OCs for contraception, and who otherwise does not have a contraindication to their use, there is insufficient evidence to recommend for or against a course of OCs solely for ovarian cancer prevention, regardless of her age or the potential duration of use. The estimated net benefits of OC use on mortality are equally distributed between prevention of ovarian cancer (relatively low incidence but high mortality), colorectal cancer (intermediate incidence and mortality), and endometrial cancer (high incidence but low mortality), while the net harms are driven by breast cancer (high incidence but relatively low mortality). In terms of incidence, the net benefits of OC use are largely driven by endometrial and colorectal cancer, while the net harms are largely due to the increased incidence of breast cancer. We did not include the potential impact of specific harms on quality of life—for example, a stroke at an early age, even if less likely to be fatal, may have a profound negative impact on quality of life.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
BMI	body mass index
BRCA	breast cancer genetic mutation
BSO	bilateral salpingo-oophorectomy
BTL	bilateral tubal ligation
CDC	Centers for Disease Control and Prevention
CI	confidence interval
DMV	Department of Motor Vehicles
DVT	deep venous thrombosis
ER	estrogen receptor
FIGO	International Federation of Gynecology and Obstetrics
GCT	granulosa cell tumor
HPV	human papilloma virus
HR	hazard ratio
HRT	hormone replacement therapy
IRR	incidence rate ratio
IUD	intrauterine device
KQ	Key Question
MI	myocardial infarction
mo	month/months
NA	not applicable
NCHS	National Center for Health Statistics
NHB	net health benefits
NIS	Nationwide Inpatient Sample
NMB	net monetary benefits
NNH	number needed to harm
NNP	number needed to prevent
NR	not reported
NS	nonsignificant
NSFG	National Survey of Family Growth
NZ	New Zealand
OC	oral contraceptive
OR	odds ratio
PE	pulmonary embolism
PICOTS	population, interventions, comparators, outcomes, timing, settings
PR	progesterone receptor
QALY	quality-adjusted life year
RR	risk ratio
SEER	Surveillance, Epidemiology, and End Results registry
SOE	strength of evidence
TEP	Technical Expert Panel
UK	United Kingdom
VTE	venous thromboembolism

WHO	World Health Organization
WTP	willingness to pay
yr	year/years

Appendix A. Exact Search Strings

PubMed® search strategy (June 29, 2012)

((((("contraceptive agents, female"[MeSH Terms] OR ("contraceptive"[All Fields] AND "agents"[All Fields] AND "female"[All Fields]) OR "female contraceptive agents"[All Fields] OR ("female"[All Fields] AND "contraceptive"[All Fields] AND "agents"[All Fields]) OR "contraceptive agents, female"[Pharmacological Action]) OR ("contraceptives, oral"[MeSH Terms] OR ("contraceptives"[All Fields] AND "oral"[All Fields]) OR "oral contraceptives"[All Fields] OR ("oral"[All Fields] AND "contraceptives"[All Fields]) OR "contraceptives, oral"[Pharmacological Action])) AND (("ovarian neoplasms"[MeSH Terms] OR ("ovarian"[All Fields] AND "neoplasms"[All Fields]) OR "ovarian neoplasms"[All Fields] OR ("ovarian"[All Fields] AND "cancer"[All Fields]) OR "ovarian cancer"[All Fields]) OR ("granulosa cell tumour"[All Fields] OR "granulosa cell tumor"[MeSH Terms] OR ("granulosa"[All Fields] AND "cell"[All Fields] AND "tumor"[All Fields]) OR "granulosa cell tumor"[All Fields]) OR ("luteoma"[MeSH Terms] OR "luteoma"[All Fields]) OR ("meigs syndrome"[MeSH Terms] OR ("meigs"[All Fields] AND "syndrome"[All Fields]) OR "meigs syndrome"[All Fields]) OR ("sertoli leydig cell tumour"[All Fields] OR "sertoli-leydig cell tumor"[MeSH Terms] OR ("sertoli-leydig"[All Fields] AND "cell"[All Fields] AND "tumor"[All Fields]) OR "sertoli-leydig cell tumor"[All Fields] OR ("sertoli"[All Fields] AND "leydig"[All Fields] AND "cell"[All Fields] AND "tumor"[All Fields]) OR "sertoli leydig cell tumor"[All Fields] OR "Sertoli-Leydig Cell Tumor"[MeSH Terms] OR ("Sertoli-Leydig"[All Fields] AND "Cell"[All Fields] AND "Tumor"[All Fields]) OR "Sertoli-Leydig Cell Tumor"[All Fields] OR ("sertoli"[All Fields] AND "leydig"[All Fields] AND "cell"[All Fields] AND "tumor"[All Fields]) OR "sertoli leydig cell tumor"[All Fields] OR "Sertoli Leydig Cell Tumor"[MeSH Terms] OR ("Sertoli"[All Fields] AND "Leydig"[All Fields] AND "Cell"[All Fields] AND "Tumor"[All Fields]) OR "Sertoli Leydig Cell Tumor"[All Fields] OR ("sertoli"[All Fields] AND "leydig"[All Fields] AND "cell"[All Fields] AND "tumor"[All Fields])) OR ("thecoma"[MeSH Terms] OR "thecoma"[All Fields]) OR "ovarian cysts"[MeSH Terms:noexp] OR ("pregnancy"[MeSH Terms] OR "pregnancy"[All Fields]) OR ("venous thrombosis"[MeSH Terms] OR ("venous"[All Fields] AND "thrombosis"[All Fields]) OR "venous thrombosis"[All Fields] OR ("deep"[All Fields] AND "vein"[All Fields] AND "thrombosis"[All Fields]) OR "deep vein thrombosis"[All Fields]) OR DVT[All Fields] OR ("budd-chiari syndrome"[MeSH Terms] OR ("budd-chiari"[All Fields] AND "syndrome"[All Fields]) OR "budd-chiari syndrome"[All Fields] OR ("budd"[All Fields] AND "chiari"[All Fields] AND "syndrome"[All Fields]) OR "budd chiari syndrome"[All Fields]) OR ("retinal vein occlusion"[MeSH Terms] OR ("retinal"[All Fields] AND "vein"[All Fields] AND "occlusion"[All Fields]) OR "retinal vein occlusion"[All Fields]) OR ("thrombophlebitis"[MeSH Terms] OR "thrombophlebitis"[All Fields]) OR ("venous thromboembolism"[MeSH Terms] OR ("venous"[All Fields] AND "thromboembolism"[All Fields]) OR "venous thromboembolism"[All Fields]) OR (("veins"[MeSH Terms] OR "veins"[All Fields] OR "venous"[All Fields]) AND ("thromboembolism"[MeSH Terms] OR "thromboembolism"[All Fields] OR ("thromboembolic"[All Fields] AND "event"[All Fields]) OR "thromboembolic event"[All Fields])) OR VTE[All Fields] OR ("cerebrovascular disorders"[MeSH Terms] OR ("cerebrovascular"[All Fields] AND "disorders"[All Fields]) OR "cerebrovascular disorders"[All Fields]) OR ("stroke"[MeSH Terms] OR "stroke"[All Fields]) OR ((("brain"[MeSH Terms] OR "brain"[All Fields]) OR ("cerebrum"[MeSH Terms] OR "cerebrum"[All Fields] OR "cerebral"[All Fields] OR "brain"[MeSH Terms] OR "brain"[All Fields])) AND (("infarction"[MeSH Terms] OR "infarction"[All Fields]) OR ("ischaemia"[All Fields] OR "ischemia"[MeSH Terms] OR "ischemia"[All Fields]) OR ("embolism"[MeSH Terms] OR "embolism"[All Fields]) OR ("thrombosis"[MeSH Terms] OR "thrombosis"[All Fields]))) OR ("meningioma"[MeSH Terms] OR "meningioma"[All Fields]) OR ("melanoma"[MeSH Terms] OR "melanoma"[All Fields]) OR ("breast neoplasms"[MeSH Terms] OR ("breast"[All Fields] AND "neoplasms"[All Fields]) OR "breast neoplasms"[All Fields] OR ("breast"[All Fields] AND "cancer"[All Fields]) OR "breast cancer"[All Fields]) OR ("uterine neoplasms"[MeSH Terms] OR ("uterine"[All Fields] AND "neoplasms"[All Fields]) OR "uterine neoplasms"[All Fields]) OR ("uterine cervical neoplasms"[MeSH Terms] OR ("uterine"[All Fields] AND "cervical"[All Fields] AND "neoplasms"[All Fields]) OR "uterine cervical neoplasms"[All Fields] OR ("cervical"[All Fields] AND "cancer"[All Fields]) OR "cervical cancer"[All Fields]) OR ("endometrial neoplasms"[MeSH Terms] OR ("endometrial"[All Fields] AND "neoplasms"[All Fields]) OR "endometrial neoplasms"[All Fields] OR ("endometrial"[All Fields] AND "cancer"[All Fields])

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Letter[ptyp] OR Case Reports[ptyp])) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms]) AND (English[lang] AND ("1990"[PDAT] : "3000"[PDAT]))

Embase® search strategy (June 29, 2012)

Platform: Embase.com

[embase]/lim NOT [medline]/lim AND ('oral contraceptive agent'/exp OR 'oral contraceptives') AND ('ovary tumor'/exp OR 'ovarian cancer':ti OR 'ovarian cancer':ab OR 'granulosa cell tumor':ti OR 'granulosa cell tumor':ab OR dysgerminoma:ti OR dysgerminoma:ab OR 'meigs syndrome':ti OR 'meigs syndrome':ab OR luteoma:ti OR luteoma:ab OR 'androblastoma'/exp OR 'sertoli-leydig cell tumor':ti OR 'sertoli-leydig cell tumor':ab OR thecoma:ti OR thecoma:ab OR 'ovary cyst'/de OR 'ovarian cyst':ti OR 'ovarian cyst':ab OR 'pregnancy'/exp OR pregnancy:ti OR pregnancy:ab OR 'vein thrombosis'/exp OR 'venous thrombosis':ti OR 'venous thrombosis':ab OR 'deep vein thrombosis':ti OR 'deep vein thrombosis':ab OR dvt:ti OR dvt:ab OR 'budd chiari syndrome'/exp OR 'budd chiari syndrome':ti OR 'budd chiari syndrome':ab OR 'vein occlusion'/exp OR 'retinal vein occlusion':ti OR 'retinal vein occlusion':ab OR thrombophlebitis:ti OR thrombophelbitis:ab OR 'venous thromboembolism'/exp OR 'venous thromboembolism':ti OR 'venous thromboembolism':ab OR 'venous thromboembolic event':ti OR 'venous thromboembolic event':ab OR vte:ti OR vte:ab OR 'cerebrovascular disease'/exp OR stroke:ti OR stroke:ab OR (brain:ti OR brain:ab OR cerebral:ti OR cerebral:ab AND (infarction:ti OR infarction:ab OR ischemia:ti OR ischemia:ab OR embolism:ti OR embolism:ab OR thrombosis:ti OR thrombosis:ab OR hemorrhage:ti OR hemorrhage:ab OR hematoma:ti OR hematoma:ab)) OR 'meningioma'/exp OR meningioma:ti OR meningioma:ab OR 'melanoma'/exp OR melanoma:ti OR melanoma:ab OR 'breast cancer'/exp OR 'breast cancer':ti OR 'breast cancer':ab OR 'uterus cancer'/exp OR 'uterine cancer':ti OR 'uterine cancer':ab OR 'uterine cervix cancer'/exp OR 'cervical cancer':ti OR 'cervical cancer':ab OR 'endometrium cancer'/exp OR 'endometrial cancer':ti OR 'endometrial cancer':ab OR 'endometriosis'/exp OR endometriosis:ti OR endometriosis:ab OR 'endometrium hyperplasia'/exp OR 'endometrial hyperplasia':ti OR 'endometrial hyperplasia':ab OR menorrhagia:ti OR menorrhagia:ab OR metrorrhagia:ti OR metrorrhagia:ab OR hypermenorrhea:ti OR hypermenorrhea:ab OR 'dysfunctional uterine bleeding':ti OR 'dysfunctional uterine bleeding':ab OR 'menstruation disorder'/exp OR amenorrhea:ti OR amenorrhea:ab OR oligomenorrhea:ti OR oligomenorrhea:ab OR dysmenorrhea:ti OR dysmenorrhea:ab OR 'premenstrual dysphoric disorder':ti OR 'premenstrual dysphoric disorder':ab OR pmdd:ti OR pmdd:ab OR 'premenstrual syndrome':ti OR 'premenstrual syndrome':ab OR pms:ti OR pms:ab OR 'painful menstruation':ti OR 'painful menstruation':ab OR 'menstrual pain':ti OR 'menstrual pain':ab OR 'uterus bleeding'/exp OR 'uterine hemorrhage':ti OR 'uterine hemorrhage':ab OR 'uterine bleeding':ti OR 'uterine bleeding':ab OR 'acne'/exp OR acne:ti OR acne:ab OR 'colon cancer'/exp OR 'colon cancer':ti OR 'colon cancer':ab OR 'colorectal cancer':ti OR 'colorectal cancer':ab OR 'rectum cancer'/exp OR 'rectal cancer':ti OR 'rectal cancer':ab OR 'anus cancer'/exp OR 'anus cancer':ti OR 'anus cancer':ab OR 'anal cancer':ti OR 'anal cancer':ab OR 'heart infarction'/exp OR 'heart attack':ti OR 'heart attack':ab OR 'myocardial infarction':ti OR 'myocardial infarction':ab OR 'liver cancer'/exp OR 'liver cancer':ti OR 'liver cancer':ab OR 'mortality'/exp OR mortality:ti OR mortality:ab OR 'death rate':ti OR 'death rate':ab OR 'survival'/exp OR survival:ti OR survival:ab OR 'fatality'/exp OR fatality:ti OR fatality:ab OR 'life expectancy':ti OR 'life expectancy':ab OR 'life expectancy'/exp) AND ('controlled study'/exp OR 'randomized controlled trial':ti OR 'randomized controlled trial':ab OR randomized:ti OR randomized:ab OR placebo:ti OR placebo:ab OR randomly:ti OR randomly:ab OR trial:ti OR 'cohort analysis'/exp OR 'controlled clinical trial'/exp OR 'case control study'/exp OR 'intervention study'/exp OR 'longitudinal study'/exp OR 'prospective study'/exp OR 'cohort study':ti OR 'cohort study':ab OR longitudinal:ti OR longitudinal:ab OR 'follow up':ti OR 'follow up':ab OR prospective:ti OR prospective:ab OR 'case control':ti OR 'case control':ab OR 'systematic review'/exp OR 'meta analysis'/exp) NOT 'case report'/exp AND [humans]/lim AND [english]/lim AND [1990-2011]/py

Cochrane search strategy (June 29, 2012)

Platform: Wiley

Database searched: Cochrane Database of Systematic Reviews

Oral contraceptives [in title-abstract-keywords]

ClinicalTrials.gov search strategy (December 15, 2012)

Platform: www.clinicaltrials.gov

Search #1:

Intervention: oral contraceptive
Outcome Measures: ovarian cancer OR myocardial infarction OR MI OR thromboembolism OR VTE OR PE OR DVT OR pulmonary embolism OR stroke OR cervical cancer OR endometrial cancer OR breast cancer OR colorectal cancer

Search #2:

General search terms (all fields): oral contraceptive AND ovarian cancer

Appendix B. Data Abstraction Elements

I. Study Characteristics

- Other articles used in this abstraction
- Last Name of First Author
- Publication Year
- Study dates
  - Date enrollment started
  - Date follow-up ended
- Study site information
  - Single center, multicenter, or pooled analysis
  - If single center, city and state (U.S.) or city and country (outside U.S.)
  - If multicenter
    - Number of sites
    - Location/ geographic region(s) (Select all that apply)
      - U.S.
      - Canada
      - U.K.
      - Europe
      - S. America
      - Asia
      - Africa
      - Australia/New Zealand
      - Unclear/Not reported
      - Other (specify)
  - If pooled analysis, number of studies included
- Funding (Select all that apply)
  - Government
  - Private
  - Foundation
  - Industry
  - Unclear/Not reported
  - Other (specify)
- Indications for OCs (Select all that apply, assume contraception if not otherwise stated)
  - Contraception
  - Prevention of ovarian cancer
  - Other stated indication (specify)
- Outcomes Assessed (Select all that apply)
  - Ovarian cancer (Select all that apply)
    - Invasive
    - Borderline/Low Malignant Potential
    - Unclear/Not reported
  - Breast cancer
  - Colorectal cancer
  - Cervical cancer
  - Endometrial cancer
  - Other cancer (specify)

- Stroke (Select all that apply)
  - Hemorrhagic stroke
  - Thrombotic stroke
  - Unclear/Not reported
- Myocardial infarction
- Deep venous thrombosis
- Pulmonary embolism

- Study design
  - Randomized controlled trial (RCT)
  - Cohort
  - Case-control
  - Patient-level pooled analysis (Select design of component studies)
    - Case-control
    - Cohort
- Comments

II. Cohort Study Details

- Total number of subjects (Enter total N for each category, NR for not reported, or NA for not applicable)
  - Number reported as (Select one): Subjects/Person-years
  - Record the following for both OCP exposed and OCP non-exposed groups:
    - Initially screened
    - Enrolled
    - Excluded for other specified reason
    - Lost to follow-up
    - N for analysis
    - Source of subjects reported (Yes/NR)
      - If yes, select source
        - Hospital
        - Population
        - Other (specify)
- Subject Age Reported (Yes/NR)
  - Record age in years for both OCP exposed and OCP non-exposed groups
    - Mean
    - Median
    - SD
    - Min. age
    - Max. age
    - 25% IQR
    - 75% IQR
    - Categorical reporting (specify)
    - Other (specify)
  - p-value between groups
- Subject Race Reported (Yes/NR)
  - Record the following for both OCP exposed and OCP non-exposed groups
    - American Indian or Alaska Native (N or %)
    - Asian (N or %)
    - Black or African American (N or %)
    - Hispanic (N or %)
    - Native Hawaiian or other Pacific Islander (N or %)

        - White (N or %)
        - Multiracial (N or %)
    - p-values between groups
- Medical History
    - Record the following for both OCP exposed and OCP non-exposed groups
        - Age at menarche reported (Yes/NR)
            - Mean
            - SD
            - Min age
            - Max age
            - Median
            - 25% IQR
            - 75% IQR
            - Categorical reporting (specify)
            - Other (specify)
        - Gravidity reported (Yes/NR)
            - Mean
            - SD
            - Min age
            - Max age
            - Median
            - 25% IQR
            - 75% IQR
            - Categorical reporting (specify)
            - Other (specify)
        - Parity reported (Yes/NR)
            - Mean
            - SD
            - Min age
            - Max age
            - Median
            - 25% IQR
            - 75% IQR
            - Categorical reporting (specify)
            - Other (specify)
        - Menopausal status reported (Yes/NR)
            - Premenopausal (%)
            - Postmenopausal (%)
            - Perimenopausal (%)
            - Unknown
        - Breastfeeding reported (Yes/NR)
            - Yes (%)
            - No (%)
        - Hysterectomy reported (Yes/NR)
            - Yes
            - No
        - Oophorectomy reported (Yes/NR)
            - Yes

- No
- Excluded

- Family history of ovarian cancer reported (Yes/NR)
  - Yes
  - No
- BrCA1 status reported (Yes/NR)
  - Positive
  - Negative
- BrCA2 status reported (Yes/NR)
  - Positive
  - Negative
- Other genetic risk factor reported (Yes/NR)
  - Family history of primary outcome
  - Factor V Leiden
  - Other thrombogenic genotype
  - Other genetic risk factor (specify)

- p-values between groups

- Contraception data reported (Yes/NR)
  - Non-Oral Contraceptive Group(s)
    - Record N and % for the following:
      - Barrier method
      - IUD
      - Injectable/implantable hormones
      - Female sterilization
      - Male sterilization
  - Oral Contraceptives
    - For each OC type reported, record the following:
      - Estrogen formulation (Select one)
        - Estradiol valerate
        - Ethinyl estradiol
        - Mestranol
        - None
      - Estrogen Dose (Select one)
        - High
        - Low
        - Not applicable
      - Progestin formulation (Select one)
        - Desogestrel
        - Dienogest
        - Drospirenone
        - Ethynodiol diacetate
        - Levonorgestrel
        - Norethindrone
        - Norethindrone diacetate
        - Norgestimate
        - Norgestrel
      - Progestin Generation (Select one)
        - 1
        - 2

        - 3
        - 4
        - Unclear/Not Reported
    - Progestin Dose (Select one)
        - High
        - Low
        - Not applicable
    - N and % of subjects using this type of OC
- Duration of OC use (record the following, if reported):
    - Minimum
    - Maximum
    - Mean
    - Median
    - SD
    - p-value
    - Categorical reporting (specify)
- Ages OCs used (record the following, if reported):
    - Minimum
    - Maximum
    - Mean
    - Median
    - SD
    - p-value
    - Categorical reporting (specify)
- Time since last OC use & assessment of outcome status (record the following, if reported):
    - Minimum
    - Maximum
    - Mean
    - Median
    - SD
    - p-value
    - Categorical reporting (specify)
- Pattern of OC use (record the following, if reported):
    - Number of episodes of use
    - Number of continuous months
    - Minimum
    - Maximum
    - Mean
    - Median
    - SD
    - p-value
    - Categorical reporting (specify)
- Number of months between OC uses (record the following, if reported):
    - Minimum
    - Maximum
    - Mean
    - Median

- SD
- p-value
- Categorical reporting (specify)

- Comments

III. Case-Control Study Details

- Total number of subjects (Enter total N for each category, NR for not reported, or NA for not applicable)
  - Number reported as (Select one): Subjects/Person-years
  - Record the following for both cases and controls:
    - Initially screened
    - Declined to participate
    - Excluded based on criteria
    - N for analysis
    - Source of subjects reported (Yes/NR)
      - If yes, select source
        - Hospital
        - Population
        - Other (specify)
- Subject Age Reported (Yes/NR)
  - Record age in years for both cases and controls
    - Mean
    - Median
    - SD
    - Min. age
    - Max. age
    - 25% IQR
    - 75% IQR
    - Categorical reporting (specify)
    - Other (specify)
  - p-value between groups
- Subject Race Reported (Yes/NR)
  - Record the following for both cases and controls
    - American Indian or Alaska Native (N or %)
    - Asian (N or %)
    - Black or African American (N or %)
    - Hispanic (N or %)
    - Native Hawaiian or other Pacific Islander (N or %)
    - White (N or %)
    - Multiracial (N or %)
  - p-values between groups
- Medical History
  - Record the following for both cases and controls
    - Age at menarche reported (Yes/NR)
      - Mean
      - SD
      - Min age
      - Max age
      - Median
      - 25% IQR

    - 75% IQR
    - Categorical reporting (specify)
    - Other (specify)
- Gravidity reported (Yes/NR)
    - Mean
    - SD
    - Min age
    - Max age
    - Median
    - 25% IQR
    - 75% IQR
    - Categorical reporting (specify)
    - Other (specify)
- Parity reported (Yes/NR)
    - Mean
    - SD
    - Min age
    - Max age
    - Median
    - 25% IQR
    - 75% IQR
    - Categorical reporting (specify)
    - Other (specify)
- Menopausal status reported (Yes/NR)
    - Premenopausal (%)
    - Postmenopausal (%)
    - Perimenopausal (%)
    - Unknown
- Breastfeeding reported (Yes/NR)
    - Yes (%)
    - No (%)
- Hysterectomy reported (Yes/NR)
    - Yes
    - No
- Oophorectomy reported (Yes/NR)
    - Yes
    - No
    - Excluded
- Family history of ovarian cancer reported (Yes/NR)
    - Yes
    - No
- BrCA1 status reported (Yes/NR)
    - Positive
    - Negative
- BrCA2 status reported (Yes/NR)
    - Positive
    - Negative
- Other genetic risk factor reported (Yes/NR)

- Family history of primary outcome
- Factor V Leiden
- Other thrombogenic genotype
- Other genetic risk factor (specify)

- p-values between groups

- Contraception data reported (Yes/NR)
  - Record the following for both cases and controls:
    - Record N and % of subjects utilizing the following non-OC contraceptive methods:
      - Barrier method
      - IUD
      - Injectable/implantable hormones
      - Female sterilization
      - Male sterilization
    - Oral Contraceptives
      - For each OC type reported, record the following:
        - Estrogen formulation (Select one)
          - Estradiol valerate
          - Ethinyl estradiol
          - Mestranol
          - None
        - Estrogen Dose (Select one)
          - High
          - Low
          - Not applicable
        - Progestin formulation (Select one)
          - Desogestrel
          - Dienogest
          - Drospirenone
          - Ethynodiol diacetate
          - Levonorgestrel
          - Norethindrone
          - Norethindrone diacetate
          - Norgestimate
          - Norgestrel
        - Progestin Generation (Select one)
          - 1
          - 2
          - 3
          - 4
          - Unclear/Not Reported
        - Progestin Dose (Select one)
          - High
          - Low
          - Not applicable
        - N and % of subjects using this type of OC
    - Duration of OC use (record the following, if reported):
      - Minimum
      - Maximum
      - Mean

        - Median
        - SD
        - p-value
        - Categorical reporting (specify)
    - Ages OCs used (record the following, if reported):
        - Minimum
        - Maximum
        - Mean
        - Median
        - SD
        - p-value
        - Categorical reporting (specify)
    - Time since last OC use & assessment of outcome status (record the following, if reported):
        - Minimum
        - Maximum
        - Mean
        - Median
        - SD
        - p-value
        - Categorical reporting (specify)
    - Pattern of OC use (record the following, if reported):
        - Number of episodes of use
        - Number of continuous months
        - Minimum
        - Maximum
        - Mean
        - Median
        - SD
        - p-value
        - Categorical reporting (specify)
    - Number of months between OC uses (record the following, if reported):
        - Minimum
        - Maximum
        - Mean
        - Median
        - SD
        - p-value
        - Categorical reporting (specify)
- Comments

IV. Outcomes Reporting Form

- Select outcome being reported
    - Ovarian Cancer
    - Breast Cancer
    - Colorectal Cancer
    - Cervical Cancer
    - Endometrial Cancer

- Deep venous thrombosis
- Pulmonary embolus
- Stroke
- Myocardial infarction
- Is this data for disease incidence or disease-specific mortality?
  - Incidence
  - Disease-specific mortality
- Is this data for a special population (Yes/No)
  - If yes, indicate the population
- Is this data for a subgroup of the overall study population (Yes/No)
  - If yes, indicate the subgroup population

- For this outcome
  - Enter N analyzed for cases or OC exposed group
  - Enter N analyzed for controls or OC non-exposed group
  - Record the following data for OC ever use
    - Crude OR and 95% CI
    - Adjusted OR and 95% CI
      - Indicate adjustment factors:
        - Age
        - Race
        - Parity
        - Menopausal status
        - BMI
        - Family History
        - Age at menarche
        - Smoking
        - Breastfeeding
        - Other (specify)
  - Data reported by OC duration (Yes/NR)
    - Does this data represent recency of use (Yes/No)
    - Record the following for all duration categories reported:
      - Crude OR and 95% CI
      - Adjusted OR and 95% CI
        - Indicate adjustment factors:
          - Age
          - Race
          - Parity
          - Menopausal status
          - BMI
          - Family History
          - Age at menarche
          - Smoking
          - Breastfeeding
          - Other (specify)
  - Data reported by age at first use (Yes/NR)
    - Record the following for all categories reported:
      - Crude OR and 95% CI
      - Adjusted OR and 95% CI
        - Indicate adjustment factors:
          - Age

- Race
- Parity
- Menopausal status
- BMI
- Family History
- Age at menarche
- Smoking
- Breastfeeding
- Other (specify)

- Data reported by age at last use (Yes/NR)
  - Record the following for all categories reported:
    - Crude OR and 95% CI
    - Adjusted OR and 95% CI
      - Indicate adjustment factors:
        - Age
        - Race
        - Parity
        - Menopausal status
        - BMI
        - Family History
        - Age at menarche
        - Smoking
        - Breastfeeding
        - Other (specify)
- Data reported by formulation (Yes/NR)
  - Record the following for all categories reported:
    - Crude OR and 95% CI
    - Adjusted OR and 95% CI
      - Indicate adjustment factors:
        - Age
        - Race
        - Parity
        - Menopausal status
        - BMI
        - Family History
        - Age at menarche
        - Smoking
        - Breastfeeding
        - Other (specify)
- Subgroup/Stratified Analyses performed? (Yes/No)
- Stratification Variables
  - Age
  - Race
  - Parity
  - Menopausal status
  - BMI
  - Family history
  - Other (specify)

- Comments

V. Cohort Studies Quality Assessment

- Selection Bias
  - Was there any attempt to balance the allocation between the groups? (Yes/No/Unclear)
  - Did the study apply inclusion/exclusion criteria uniformly to all comparison groups? (Yes/No/Unclear)
  - Is the selection of the comparison group appropriate? (Yes/No/Unclear)
  - Did the strategy for recruiting participants into the study differ across study groups? (Yes/No/Unclear)
  - Are baseline characteristics similar between groups? If not, did the analysis control for differences? (Yes/No/Unclear)
  - Does the design or analysis control account for important confounding and modifying variables? (Yes/No/Unclear)
- Performance Bias
  - Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?
  - Did variation from the study protocol compromise the conclusions of the study?
- Attrition Bias
  - Is the length of follow-up different between the groups?
  - Was there a high rate of differential or overall attrition?
  - Is the analysis conducted on an intention-to-treat (ITT) basis?
- Detection Bias
  - Were the outcome assessors blinded to the intervention or exposure status of participants?
  - Are the inclusion/exclusion criteria measured using valid and reliable measures, implemented consistently across all study participants?
  - Are interventions/exposures assessed using valid and reliable measures, implemented consistently across all study participants?
  - Are primary outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
  - Are confounding variables assessed using valid and reliable measures, implemented consistently across all study participants?
- Reporting Bias
  - Are the potential outcomes pre-specified by the researchers? Are all pre-specified outcomes reported?
- Record any additional comments relating to potential sources of bias or other study limitations.
- Summary Quality Rating
  - Good
  - Fair
  - Poor
  - If the study is rated as "Fair" or "Poor," provide rationale for decision.

VI. Case-Control Studies Quality Assessment

- Selection Bias
  - Did the study apply inclusion/exclusion criteria uniformly to all comparison groups? (Yes/No/Unclear)
  - Is the selection of the comparison group appropriate? (Yes/No/Unclear)
  - Does the design or analysis control account for important confounding and modifying variables? (Yes/No/Unclear)
- Performance Bias

    - Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?
    - Did variation from the study protocol compromise the conclusions of the study?
- Detection Bias
    - Were the outcome assessors blinded to the intervention or exposure status of participants?
    - Are the inclusion/exclusion criteria measured using valid and reliable measures, implemented consistently across all study participants?
    - Are interventions/exposures assessed using valid and reliable measures, implemented consistently across all study participants?
    - Are primary outcomes assessed using valid and reliable measures, implemented consistently across all study participants?
    - Are confounding variables assessed using valid and reliable measures, implemented consistently across all study participants?
- Reporting Bias
    - Are the potential outcomes pre-specified by the researchers? Are all pre-specified outcomes reported?
- Record any additional comments relating to potential sources of bias or other study limitations.
- Summary Quality Rating
    - Good
    - Fair
    - Poor
    - If the study is rated as "Fair" or "Poor," provide rationale for decision.

VII. Cohort Applicability Assessment

- Population (P)
    - Age at OC use
        - At least 25% of study population age 35 years or older
        - <25% of study population age 35 or older
    - Baseline risk for ovarian cancer
        - Risk factors described (e.g., family history)
        - Risk factors not described
- Intervention (I)
    - OC formulation
        - Currently available in U.S.
        - Not currently available in U.S.
        - NR
- Comparator (C)
    - Other contraceptive
        - Currently available in U.S.
        - Not currently available in U.S.
        - NR
- Setting (S)
    - Location
        - U.S.
        - Non-U.S.

VIII. Case-Control Applicability Assessment

- Population (P)
    - Age at OC use
        - At least 25% of study population age 35 years or older

        - <25% of study population age 35 or older
    - Baseline risk for ovarian cancer
        - Risk factors described (e.g., family history)
        - Risk factors not described
- Intervention (I)
    - OC formulation
        - Currently available in U.S.
        - Not currently available in U.S.
        - NR
- Comparator (C)
    - Other contraceptive
        - Currently available in U.S.
        - Not currently available in U.S.
        - NR
- Setting (S)
    - Location
        - U.S.
        - Non-U.S.

Appendix C. Included Studies

Althuis MD, Brogan DD, Coates RJ, et al. Breast cancers among very young premenopausal women (United States). Cancer Causes Control. 2003;14(2):151-60. PMID: 12749720.

Althuis MD, Brogan DR, Coates RJ, et al. Hormonal content and potency of oral contraceptives and breast cancer risk among young women. Br J Cancer. 2003;88(1):50-7. PMID: 12556959.

Andersen BS, Olsen J, Nielsen GL, et al. Third generation oral contraceptives and heritable thrombophilia as risk factors of non-fatal venous thromboembolism. Thromb Haemost. 1998;79(1):28-31. PMID: 9459317.

Anonymous. Acute myocardial infarction and combined oral contraceptives: results of an international multicentre case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet. 1997;349(9060):1202-9. PMID: 9130941.

Anonymous. Cardiovascular disease and use of oral and injectable progestogen-only contraceptives and combined injectable contraceptives. Results of an international, multicenter, case-control study. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Contraception. 1998;57(5):315-24. PMID: 9673838.

Anonymous. Effect of different progestagens in low oestrogen oral contraceptives on venous thromboembolic disease. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet. 1995;346(8990):1582-8. PMID: 7500749.

Anonymous. Haemorrhagic stroke, overall stroke risk, and combined oral contraceptives: results of an international, multicentre, case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet. 1996;348(9026):505-10. PMID: 8757152.

Anonymous. Ischaemic stroke and combined oral contraceptives: results of an international, multicentre, case-control study. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet. 1996;348(9026):498-505. PMID: 8757151.

Anonymous. Venous thromboembolic disease and combined oral contraceptives: results of international multicentre case-control study. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Lancet. 1995;346(8990):1575-82. PMID: 7500748.

Antoniou AC, Rookus M, Andrieu N, et al. Reproductive and hormonal factors, and ovarian cancer risk for BRCA1 and BRCA2 mutation carriers: results from the International BRCA1/2 Carrier Cohort Study. Cancer Epidemiol Biomarkers Prev. 2009;18(2):601-10. PMID: 19190154.

Austin H, Lally C, Benson JM, et al. Hormonal contraception, sickle cell trait, and risk for venous thromboembolism among African American women. Am J Obstet Gynecol. 2009;200(6):620 e1-3. PMID: 19306959.

Badawy YA and Bayoumi DM. An epidemiologic study of ovarian cancer. Part 11: Oral contraceptive use and menstrual events. J Egypt Public Health Assoc. 1992;67(5-6):579-91. PMID: 1294683.

Barinagarrementeria F, Gonzalez-Duarte A, Miranda L, et al. Cerebral infarction in young women: analysis of 130 cases. Eur Neurol. 1998;40(4):228-33. PMID: 9813407.

Barnett GC, Shah M, Redman K, et al. Risk factors for the incidence of breast cancer: do they affect survival from the disease?. J Clin Oncol. 2008;26(20):3310-6. PMID: 18612147.

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Study Groupings

Table C-1. Primary articles and companion articles grouped by study name (alphabetical)

Study Name	Primary Abstracted Article	Companion Articles*
Cancer and Steroid Hormone (CASH) Study	Gross, 1992[1]	
	Gwinn, 1990[2]	
	Maxwell, 2006[3]	
	Schildkraut, 2002[4]	
Collaborative Ovarian Cancer Group Study	Harris, 1992[5]	Steinberg, 1997[6] Whittemore, 1992[7] Whittemore, 1992[8]* Whittemore, 1992[9]*
	Hartge, 1994[10]	
	Horn-Ross, 1992[11]	
	John, 1993[12]	
European Prospective Investigation Into Cancer and Nutrition	Dossus, 2010[13]	
	Tsilidis, 2010[14]	
	Tsilidis, 2011[15]	
International Agency for Research on Cancer (IARC) Multicentric Case-Control Study	Moreno, 2002[16]	
	Hammouda, 2005[17]	
International BRCA1/2 Carrier Cohort Study	Antoniou, 2009[18]	
	Brohet, 2007[19]	
Leiden Thrombophilia Study	Bloemenkamp, 1995[20]	
	Bloemenkamp, 2000[21]	
Malignant Ovarian (MALOVA) Cancer Study	Huusom, 2006 [22] Soegaard, 2007[23]	
Myocardial Infarction Causality (MICA) Study	Dunn, 1999[24]	
	Dunn, 1999[25]	
	Dunn, 2001[26]	
Norwegian-Swedish Women's Lifestyle and Health Cohort Study	Kumle, 2004[27]	
	Kumle, 2004[28]	
Nurses' Health Study	Hankinson, 1995[29]	Colditz, 1994[30]
	Grodstein, 1996[31]	
	Tworoger, 2007[32]	
Oxford Family Planning Association (Oxford-FPA) Contraceptive Study	Mant, 1998[33]	
	Vessey, 1995[34]	
	Vessey, 2006[35]	
	Vessey, 2010[36]	Vessey, 2003[37]
Risk of Arterial Thrombosis in Relation to Oral Contraceptives (RATIO) Study	Kemmeren, 2002[38]	
	Tanis, 2001[39]	
Royal College of General Practitioners' Oral Contraceptive Study	Hannaford, 1998[40]	
	Hannaford, 2007[41]	Hannaford, 2005[42]
	Hannaford, 2010[43]	Beral, 1999[44]
Shanghai Breast Cancer Study	Fowke, 2004[45]	
	Xu, 2011[46]	
Shanghai Textile Workers Study	Rosenblatt, 2004[47]	
	Rosenblatt, 2009[48]	Wernli, 2006[49]
	Gallagher, 2011[50]	

Study Name	Primary Abstracted Article	Companion Articles*
Study of Health and Reproduction (SHARE)	Greer, 2005[51]	
	Greer, 2005[52]	
	Modugno, 2001[53]	Ness, 2000[54] Ness, 2000[55] Ness, 2001[56]
	Ness, 2000[55]	Ness, 2000[54] Ness, 2001[56] Modugno, 2001[53]
	Ness, 2001[56]	Ness, 2000[55] Modugno, 2001[53] Ness, 2000[54]
	Walker, 2002[57]	
Transnational Study on Oral Contraceptives and the Health of Young Women	Heinemann, 1997[58]	Heinemann, 1998[59] Spitzer, 1993[60]*
	Heinemann, 1999[61]	
	Lewis, 1999[62]	Lewis, 1996[63] Lewis, 1996[64] Lewis, 1997[65] Lewis, 1999[66]
	Suissa, 1997[67]	Spitzer, 1996[68]
	Suissa, 2000[69]	
Women's Environment, Cancer, and Radiation Epidemiology (WECARE) Study	Figueiredo, 2008[70]	
	Figueiredo, 2010[71]	
Women's Contraceptive and Reproductive Experiences (CARE) Study	Folger, 2007[72]	
	Ma, 2010[73]	
	Marchbanks, 2002[74]	Marchbanks, 2002[75]*
	Norman, 2003[76]	
	Marchbanks, 2012[77]	Marchbanks, 2002[74]
	Lu, 2011[78] (Presents data from both CARE and the California Teachers Study [CTS], analyzed separately)	
Women's Learning the Influence of Family and Environment (LIFE) Study	Lee, 2008[79]	
	Ma, 2006[80]	
World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception	Anonymous, 1995[81]	Anonymous, 1995[82]*
	Anonymous, 1995[83]	
	Anonymous, 1996[84]	
	Anonymous, 1996[85]	
	Anonymous, 1997[86]	
	Anonymous, 1998[87]	
	Chang, 1999[88]	
World Health Organization Collaborative Study of Neoplasia and Steroid Contraceptives	Rosenblatt, 1992[89]	
	Thomas, 1991[90]	

*Companion articles marked with an asterisk did not individually meet criteria for inclusion but were considered for supplemental information (e.g., methods data pertinent to an included study).

Table C-2. Primary articles and companion articles grouped by author (study name not applicable)

Author	Primary Abstracted Article	Companion Articles*
Althuis, 2003	Althuis, 2003[91]	Brinton, 1995[92]*
	Althuis, 2003[93]	
Badawy, 1992	Badawy, 1992[94]	Badawy, 1992[95]*
Chiaffarino, 2001	Chiaffarino, 2001[96]	
	Tavani, 2004[97]	
Jick, 2000	Jick, 2000[98]	Jick,1995[99]
	Farmer, 2000[100]	
Le Gal, 2010	Le Gal, 2010[101]	Rodger, 2008[102]*
Legnani, 2002	Legnani, 2002[103]	
	Legnani, 2004[104]	
Lidegaard, 2012	Lidegaard, 2012[105]	Lidegaard, 2002[106] Lidegaard, 1998[107]
	Lidegaard, 2011[108]	Lidegaard, 2009[109]
	Lidegaard, 2002[110]	Lidegaard, 1998[111]
	Lidegaard, 1998[112]	Lidegaard, 1999[113] Lidegaard, 1995[114] Lidegaard, 1998[107]
Newcomer, 2003	Newcomer, 2003[115]	Newcomb, 1994[116]*
Parazzini, 1991	Parazzini, 1991[117]	
	Parazzini, 2000[118]	
	Tavani, 2000[119]	
Riman, 2001	Riman, 2001[120]	
	Riman, 2002[121]	
Risch, 1996	Risch, 1996[122]	Risch, 1994[123] Risch, 1994[124]*
Sanderson, 2000	Sanderson, 2000[125]	
	Wittenberg, 1999[126]	
Siskind, 2000	Nagle, 2008[127]	
	Siskind, 2000[128]	Purdie, 2001[129]
Tryggvadóttir, 2002	Tryggvadóttir, 2002[130]	Tryggvadóttir, 2001[131]*
Tung, 2003	Lurie, 2007[132]	Goodman, 2005[133] Goodman, 2002[134]
	Lurie, 2008[135]	
	Tung, 2003[136]	
	Tung, 2005[137]	
van Vlijmen, 2007	van Vlijmen, 2007[138]	Brouwer, 2006[139]*
Wang, 2012	Wang, 2012[140]	Li, 2006[141]
	Li, 2010[142]	

*Companion articles marked with an asterisk did not individually meet criteria for inclusion but were considered for supplemental information (e.g., methods data pertinent to an included study).

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Appendix D. Excluded Studies

All studies listed below were reviewed in their full-text version and excluded for the reason shown in bold. Reasons for exclusion signify only the usefulness of the articles for this study and are not intended as criticisms of the articles.

Abstract only or full text unobtainable

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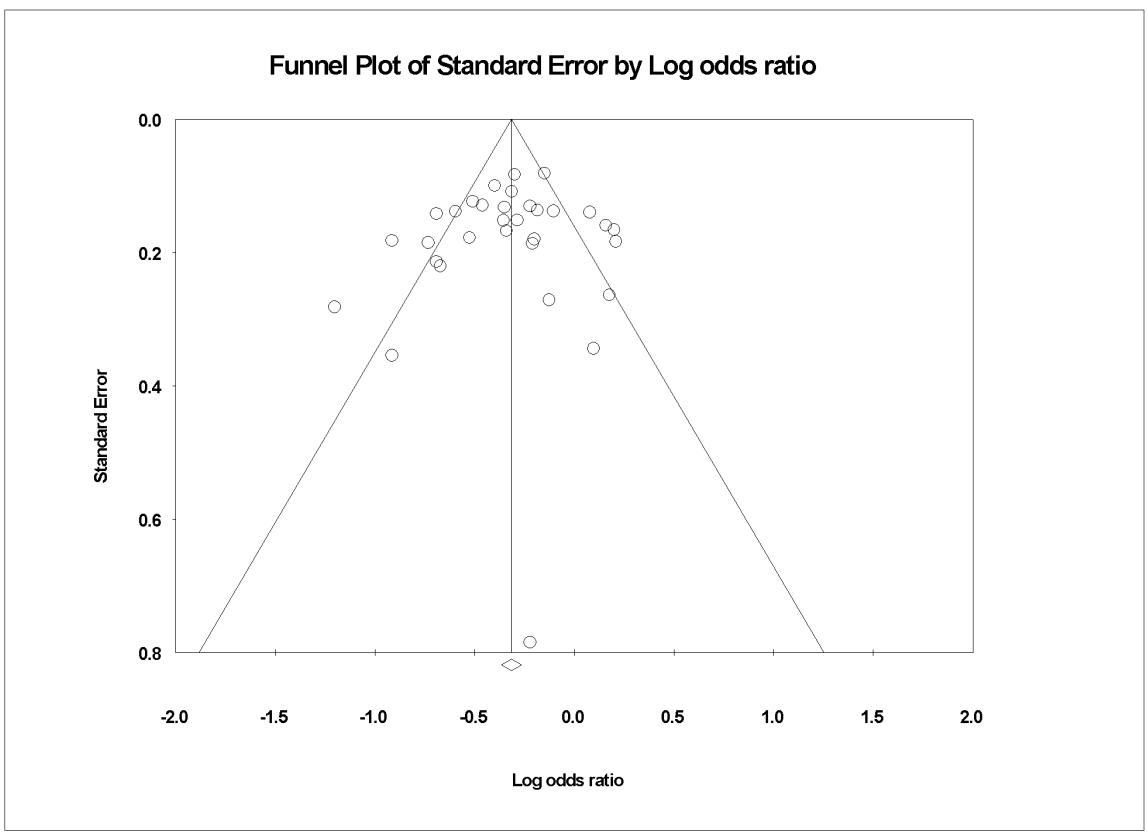
Appendix E. Analyses of Potential Publication Bias

We used Comprehensive Meta-Analysis Version 2 (Borenstein M, Hedges L, Higgins J, Rothstein H. Comprehensive Meta-analysis Version 2, Biostat, Englewood NJ [2005]) to test for potential publication bias for the outcomes described below. Figures E-1 to E-5 show the resulting funnel plot for each outcome. Note that there is no asymmetry in any of the plots.

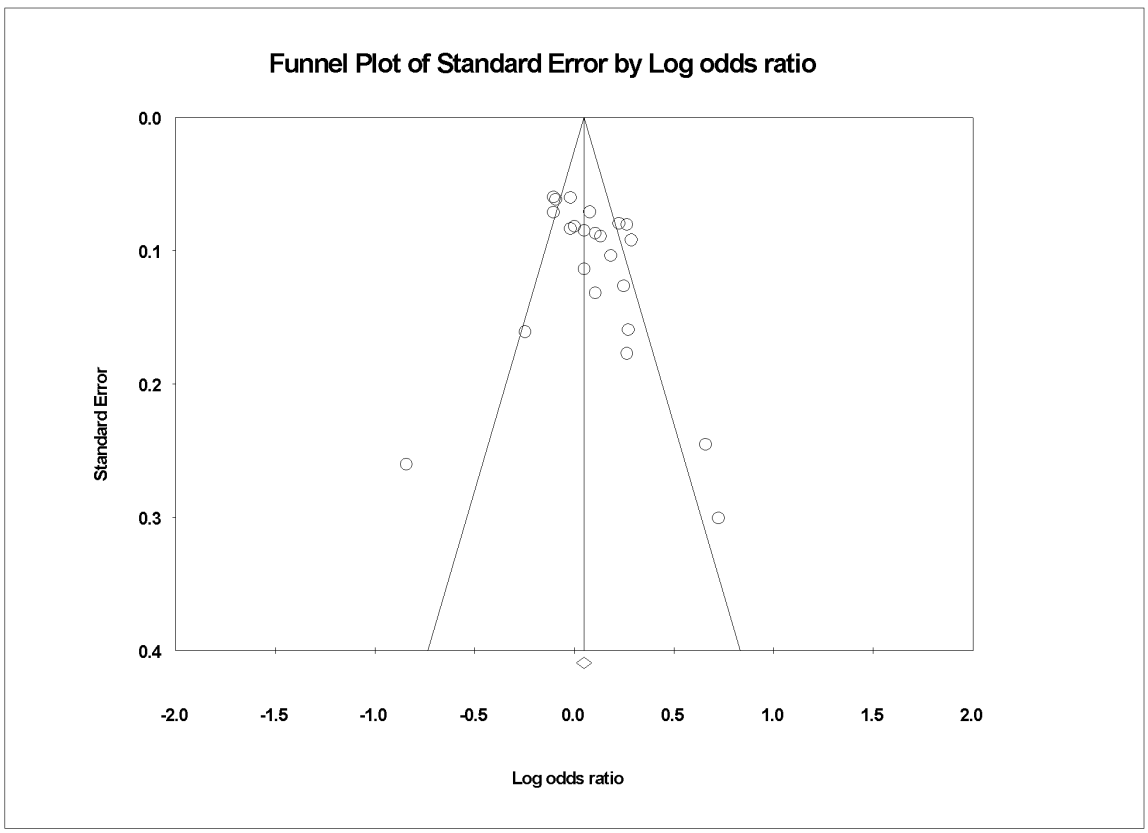
Ovarian Cancer Incidence

Figure E-1. Funnel plot for ovarian cancer incidence



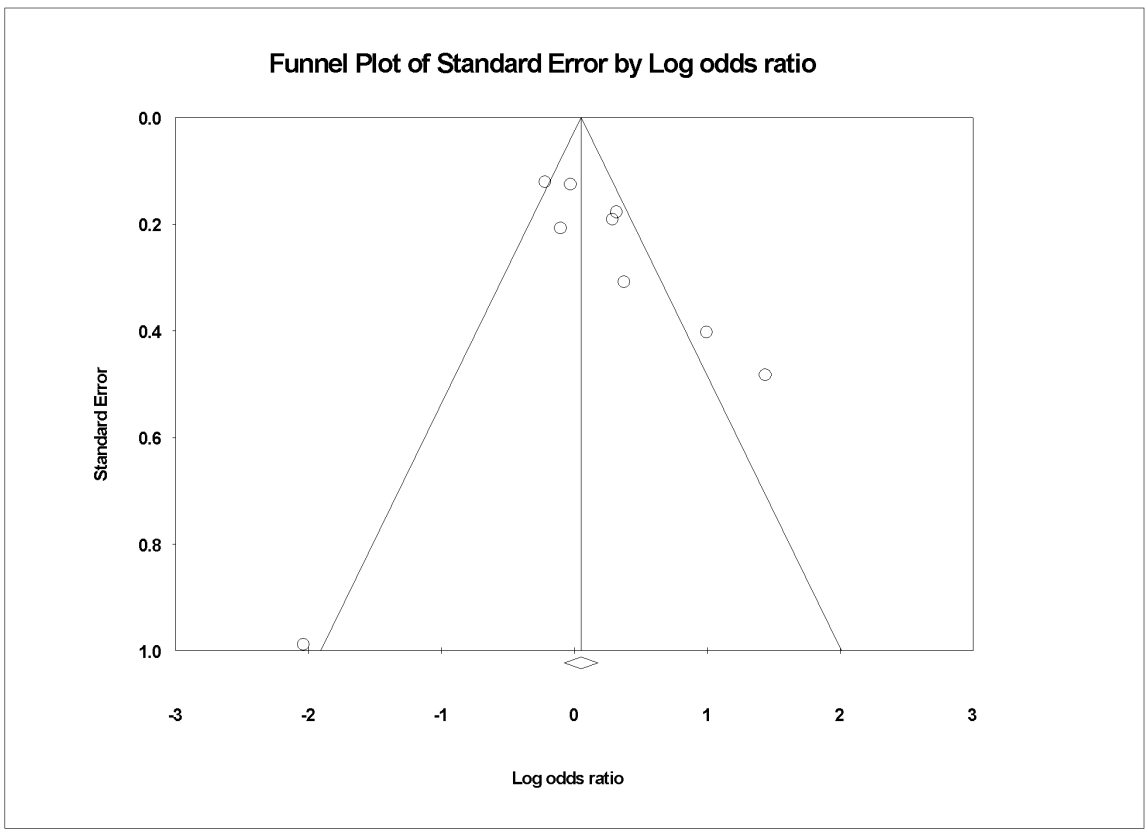
Breast Cancer Incidence

Figure E-2. Funnel plot for breast cancer incidence



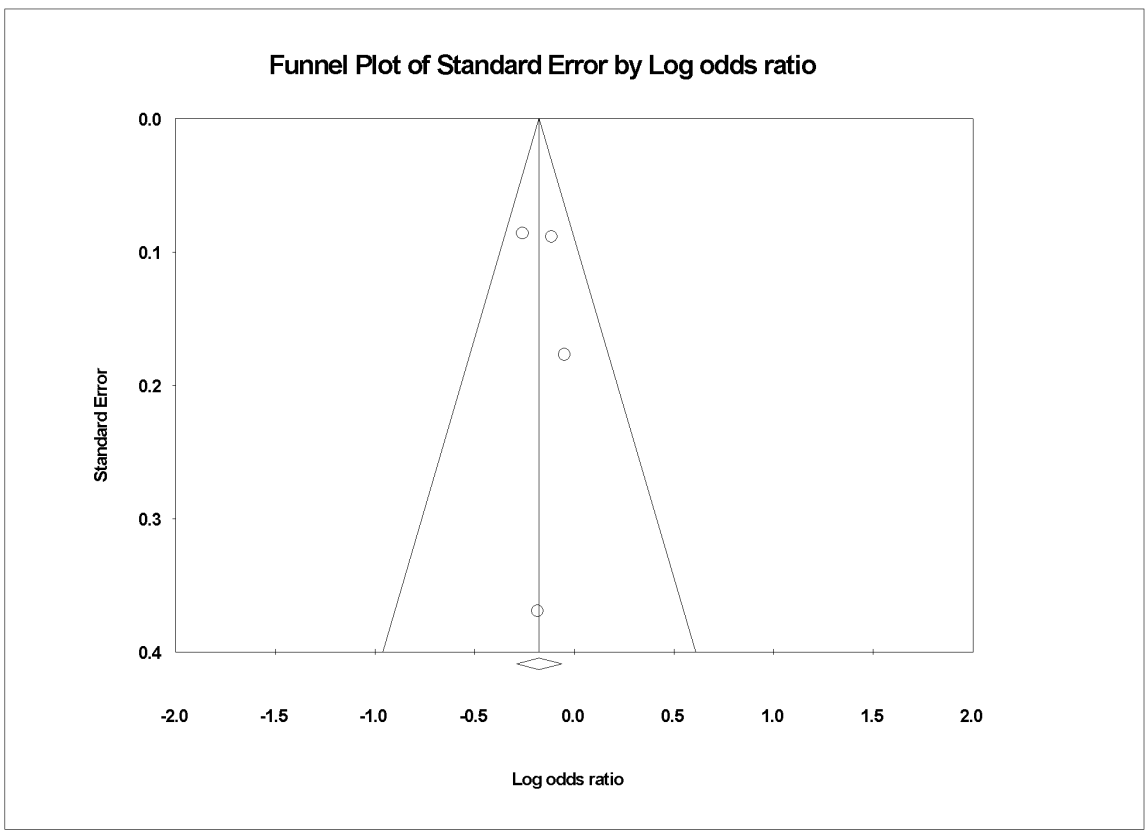
Cervical Cancer Incidence

Figure E-3. Funnel plot for cervical cancer incidence



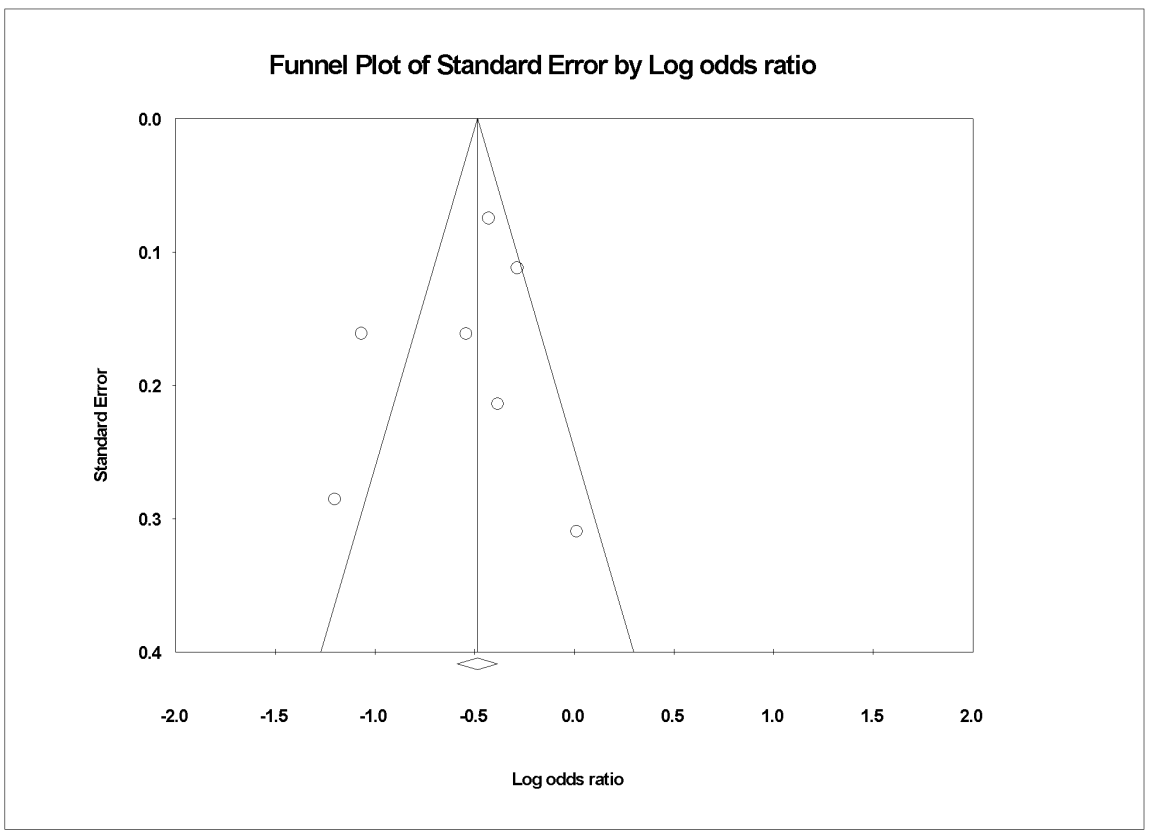
Colorectal Cancer Incidence

Figure E-4. Funnel plot for colorectal cancer incidence



Endometrial Cancer Incidence

Figure E-5. Funnel plot for endometrial cancer incidence



We also computed Begg and Mazumdar's correlation test for publication bias for each cancer incidence (Table E-1). None of the correlations were significant although breast cancer incidence was marginal.

Table 1. Begg and Mazumdar's correlation test for publication bias

Cancer Incidence	Correlation	p-value
Ovarian	-0.055	0.6458
Breast	0.289	0.0539
Cervical	0.278	0.2972
Colorectal	0.000	1.0000
Endometrial	-0.048	0.8806

Overall, there was no evidence of publication bias in the meta-analyses.

Appendix F. Model Description and Parameters

General Considerations

We previously developed a simulation model for the natural history of ovarian cancer at the population level, which has provided insights into the potential effectiveness of screening as a strategy for reducing ovarian cancer morbidity and mortality,[1,2] and many of the basic parameters and model structure used in that model are used here. However, the ovarian cancer screening model—while including such relevant parameters as age-specific oophorectomy rates, age-specific ovarian cancer incidence, stage-specific survival, between-stage transition rates derived from the observed incidence and survival data, and the potential effect of known risk factors such as BRCA mutation status—focuses primarily on ovarian cancer mortality. For the purposes of quantifying the potential tradeoffs of benefits and harms for primary prevention of ovarian cancer through the use of oral contraceptives (OCs), there were three additional major considerations for the model:

1. The eight additional outcomes (breast, cervical, colorectal, endometrial cancers; and DVT, PE, MI, and stroke) needed to be included.

2. Specific characteristics of OC use, including ages at first and last use and duration of use, may affect the association between OCs and any of the relevant outcomes; so the model needed to incorporate a mechanism for including as many aspects of OC use as possible.

3. Many aspects of reproductive history—age at menarche, age at first pregnancy, numbers of pregnancies, breast feeding history, age at menarche, number of ovulatory cycles—are related to both OC use and the risk of ovarian cancer and many of the other outcomes of interest, either as confounders or effect modifiers. The balance of benefits and harms of OC use for primary prevention of ovarian cancer for specific women may well vary based on these other factors. Therefore, ultimately, a model that incorporates a mechanism for including relevant reproductive factors and their effect on ovarian cancer risk independent of OC use may prove quite useful (as well as have applications for other areas of reproductive health).

We initially developed a model that starts at age 10 and runs through age 100, and which includes age-specific and race/ethnicity-specific probabilities of menarche (including postmenarchal anovulatory cycles), age at sexual debut, contraceptive method prevalence, age-specific fecundity, contraceptive method-specific effectiveness, pregnancy (including age-specific miscarriage rates and race/ethnicity-specific probabilities of delivery by gestational age), lactation, and hysterectomy and oophorectomy rates as well as incidence and mortality from the nine conditions of interest. Although the model generated estimates of incidence and mortality that were consistent with observed data, we ultimately opted to simplify the reproductive components of the model for the following reasons:

- The studies included in the meta-analyses almost always provided risk estimates for the association of OC use and outcomes, particularly for reproductive cancers that were adjusted for most, if not all, of the potentially relevant factors such as age at menarche and menopause. Without data on the separate parameter estimates (for example, the odds ratio for parity derived from a logistic regression model that also included OC use), modeling the joint effects was impossible.

- Even if these separate estimates were reported, there was wide disparity in how the parameters were described (categorical versus continuous, choice of categories, etc.), again making modeling difficult.

- The review of those studies which did assess joint effects of other reproductive factors did not detect significant differences.

- Although there are population-based data on the age- , race/ethnicity-, and parity-specific prevalence of the use of different contraceptive methods, as well as reasonable data on short-term method discontinuation rates, there are almost no data available for estimating the dynamics of contraceptive method switching. Because the only available data on duration of OC use did not provide data on patterns of intermittent use, we, like others, assumed that, once OC use began, women used it continuously for the specified duration (either assigned by the model or drawn from a distribution).

- Therefore,

    - We needed to assume continuous use of OCs.

    - The majority of the literature reviewed compared OC users with nonusers who used a mix of other available contraceptive methods (including no methods).

    - We found a paucity of data on the effect of contraceptive methods other than OCs and tubal ligation on ovarian cancer, our primary outcome of interest.

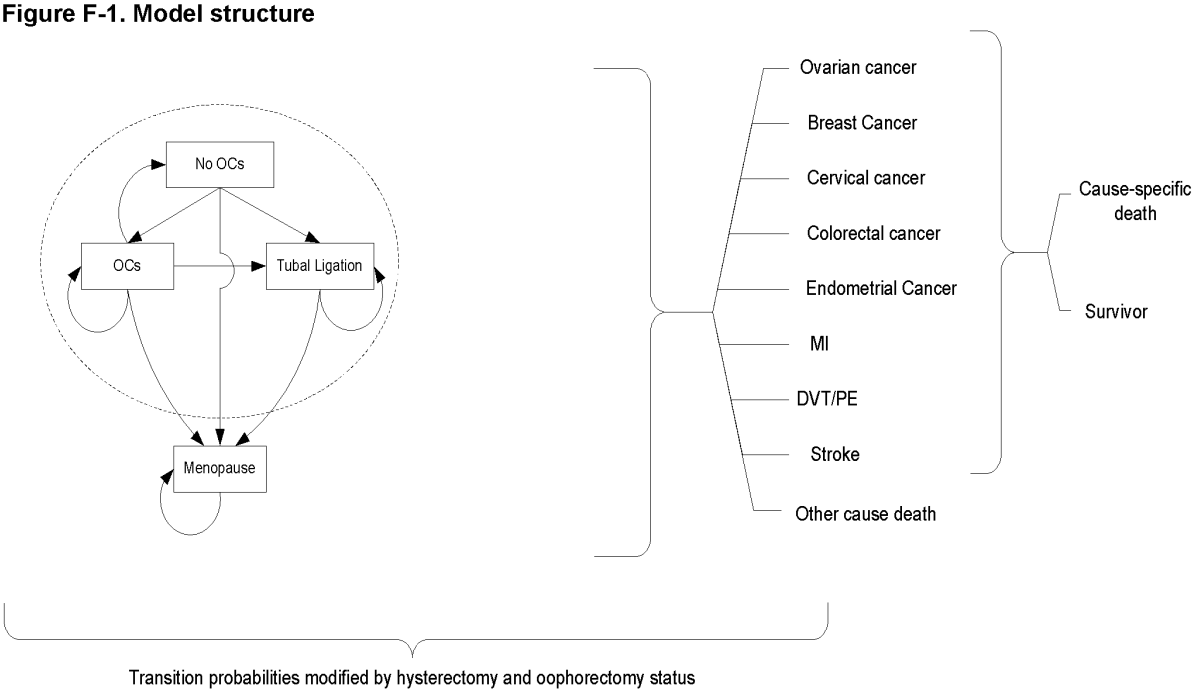
    - There were relatively small but noticeable effects of differential pregnancy rates (resulting from different contraceptive effectiveness) on outcome rates in early versions of the model, likely due to a competing risk effect; while further exploration of the implications of this effect of model structural assumptions on model output is definitely worthwhile, it was well outside the scope of work for this project.

We elected to simplify the model to just three "reproductive" states—OC users, OC nonusers, and tubal ligation for the purposes of this report. We plan further work on integrating a more detailed reproductive history into the model in future versions.

Model Structure

The model is a semi-Markov state-transition model (Figure F-1); transition probabilities are conditioned on both the current state and time (i.e., age).

Figure F-1. Model structure



We have used Markov models extensively for analysis of clinical and policy decisions involving ovarian and cervical cancer, pregnancy, and other reproductive conditions, with transition probabilities modified by time (including age and time in state for cancer diagnoses) and current state. One limitation of the "standard" Markov model, particularly when run as a deterministic model, is the inability to readily modify transition probabilities based on past events (for example, number of prior pregnancies). Because the ability to modify the probability of the relevant outcomes based on past events is a critical requirement of the model, we used microsimulation, which allows further conditioning of transition probabilities on events prior to the current cycle.

Software

The model was built in TreeAge Pro 2012 (Williamstown, MA: TreeAge, Inc.). Our decision to use TreeAge was based on our familiarity with it; most of our previous models were built using this program, which facilitated incorporating major portions of the relevant models. Iterative model building and modification, tree structure, updating parameters, using distributions, and model debugging are all relatively easy, and, given its widespread use among decision analysts, sharing of the model for purposes of review or collaboration is also straightforward. The major disadvantage of TreeAge is the relatively high computing resource requirements for complex stochastic simulations—some of the longer, more complex simulation

took more than 48 hours, even on a computer optimized for simulations. Given many of the uncertainties involved in this project, we prioritized flexibility in model building and revision over computational time. Ultimately, after a "final" structure has been identified, efficiency could be gained by recreating the model in a more efficient computing language.

Simulation Method

The model is run as a microsimulation of U.S. females, starting at a uniform age of 10 and drawing from the current U.S. racial/ethnic distribution (defined as non-Hispanic white, African-American, Hispanic, and other). By performing a microsimulation, we can use TreeAge's "tracker variable" capacity to allow the model to have "memory" of past events (e.g., time since last use of OCs, or age at menarche) in order to modify appropriate transition probabilities. Microsimulation also facilitates techniques such as value-of-information analysis for identifying future research priorities.

Cycle Length

The model has cycles of 1 month duration, with all transition probabilities adjusted appropriately (e.g., annual cancer incidences are converted to monthly probabilities).

Model States, Allowed Transitions, and Probabilities

Through the descriptions below, we refer to sources for parameter estimates, such as age- and race-specific rates, race-specific distributions of age, etc. In general, wherever possible, these data were used to define specific conditional probabilities based on age, race, or other relevant factors. For example, we used data on age- and race-specific prevalence of ever use of OCs to generate estimates of the monthly probability of starting OCs, given no prior use for each age and racial/ethnic category.

At the time of initial model building, the most recent available population data for many of our parameters at the time of initial model construction was from 2007. Unless otherwise noted, all values reflect estimates from that year. Subsequent versions of the model can be readily updated. When possible, we used point estimates and distributions defined by the data as described below.

The main report describes methods and sources for estimates of the relative risk of outcomes conditional on OC exposure, as well as the methods used to estimate incidence in exposed and unexposed women based on relative risk, prevalence of exposure, and overall incidence.

Demographic Variables

Race/ethnicity. We used U.S. Census estimates of the 10- to 14-year-old female population in 2007 (http://www.census.gov/popest/data/intercensal/national/nat2010.html), divided into 4 mutually exclusive categories: non-Hispanic whites (56.9%), non-Hispanic blacks (14.9%), Hispanic (20.3%), and non-Hispanic other race (7.9%). Because the errors around these estimates are so small, we did not model these as distributions.

***General states*:** For the purpose of estimating the overall balance of benefits and harms, nine health states potentially affected by OC use are included, in addition to other-cause mortality.

Other-cause mortality. During every cycle, individuals are at risk for age- and race-specific mortality for females. Once any of the potentially fatal states related to OCs become possible, other cause mortality is defined as age- and race-specific mortality for females minus cause-specific mortality for the five cancers, the four acute vascular events (DVT, PE, MI, and stroke), and pregnancy-related mortality.

Age-specific and race/ethnicity-specific all-cause mortality for females for 2007 was obtained from death certificate data maintained by the National Center for Health Statistics, accessed through the CDC's WONDER Web portal. We then subtracted the number of deaths attributed to malignancies of the ovary (C56), breast (C50), cervix (ICD-10 code C53), colon and rectum (C18-20), and uterine corpus (C54-55) as well as deep venous thrombosi (I82.8-I82.9), pulmonary embolism (I26), ischemic stroke (I63), and acute myocardial infarction (I21) from the total.

The monthly age- and race-specific probability of other cause mortality was then estimated by dividing the annual number of deaths in a given age/race/ethnicity stratum by the total number of women in that stratum in the Census data; this annual rate was then converted to a monthly probability by using the following formula:

$$Probability = 1 - e^{Rate*Time}$$

In order to facilitate simulations, we elected not to model these probabilities as a distribution for the purposes of the analyses presented here, but they could readily be transformed into beta distributions.

Table F-1. Deaths from causes other than ovarian, breast, cervical, colorectal, or endometrial cancers, or deep venous thrombosis, pulmonary embolism, stroke, or acute myocardial infarction, by age and race/ethnicity, U.S. females, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
5-9	647	235	251	49
10-14	760	291	239	63
15-19	2404	630	485	163
20-24	2985	926	665	223
25-29	3315	1216	698	237
30-34	3744	1415	721	280
35-39	5845	2154	916	357
40-44	9954	3111	1175	548
45-49	16489	4772	1583	738
50-54	22347	6047	2003	885
55-59	29258	6469	2405	1198
60-64	39267	6051	2726	1376
65-69	48550	6658	3271	1649
70-74	66511	7427	4245	2076
75-79	102413	7466	5855	2764
80-84	149152	6942	7016	3460
85-89	174304	4268	6319	3184
90-94	137341	2321	4433	2294
95-99	61555	1623	2030	854

Cancers: Ovarian, breast, cervical, colorectal, endometrial. For each cancer, the probability of transitioning from one of the noncancer states is the age- and race-specific incidence for women (based on national registry data), adjusted for reproductive history and use of OCs using adjusted odds ratios and/or hazard ratios obtained from the literature review. Key assumptions include:

- For all nongynecologic cancers, we assume cancer incidences are independent and non-mutually exclusive—for example, an endometrial cancer survivor will still be at risk for breast cancer at the appropriate age- and race-specific value. Other than BRCA carriers, we assume that development of one type of cancer implies an increased risk for certain other types.
- We include only invasive cancers, not *in situ* or preinvasive lesions.
- We assume that definitive therapies for ovarian, cervical, and endometrial cancer eliminate the possibility of developing another cancer of the female genital tract.
- Cancer incidences are not adjusted for screening behaviors—SEER incidence statistics, for example, represent the weighted average of cancer incidence and stage distribution among screened and unscreened populations. Although reproductive history, including contraceptive use, may affect screening behavior, we did not attempt to adjust for this.
- Cancer survival reflects the weighted age- and race-specific stage distribution—we do not separate cancers by stage at this level of the simulation. Although incorporating stage distribution in subsequent versions of the model may have value for comparing the potential effects of primary prevention of ovarian cancer with OCs to screening, modeling stage-specific outcomes would increase the complexity of the model without providing significant benefit in terms of the primary questions of interest.
- We do not separate specific cancers by histologic subtype (e.g., epithelial versus germ cell tumors of the ovary, or squamous versus adenocarcinomas of the cervix).
- After cancer diagnosis, individuals are at risk for cancer-specific mortality for 5 years, then assumed to be cured, primarily because of variable data on longer term recurrence risk. This may underestimate lifetime mortality for some cancers, particularly breast cancer.

Allowed transitions: Cancer-specific death, cancer survivor, other cancers, other cause mortality, menopause

We obtained estimates of the age-specific (in 5-year age groups) incidence of ovarian, breast, cervical, colorectal, and endometrial cancers from two sources: (1) the Surveillance, Epidemiology, and End Results (SEER) database maintained by the National Cancer Institute (http://seer.cancer.gov/canques/index.html) and (2) the Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (http://wonder.cdc.gov/wonder/help/cancernpcr-v2009.html). Cancer incidence was modeled in a similar fashion to other cause mortality, using the estimated number of cases. We converted incidence (a rate), to probabilities as described above, and assumed that the pooled odds ratios from the meta-analyses were reasonable estimates of the relative risk. For cancer, we used these

numbers and the Census population estimates to beta distributions (which are bounded between 0 and 1) for probabilistic analyses.

Table F-2. Number of ovarian cancers by age and race/ethnicity, United States, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
10-14	30	0	21	0
15-19	62	27	26	0
20-24	114	17	38	0
25-29	131	26	40	0
30-34	191	22	41	26
35-39	369	44	74	38
40-44	676	98	132	50
45-49	1263	139	156	82
50-54	1740	201	172	107
55-59	1948	188	200	81
60-64	2084	210	140	81
65-69	1885	196	135	51
70-74	1759	165	110	53
75-79	1716	148	107	31
80-85	1593	103	74	27
85+	1521	108	57	22

Table F-3. Number of breast cancers by age and race/ethnicity, United States, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
10-14	0	0	0	0
15-19	0	0	0	0
20-24	83	38	32	0
25-29	514	160	125	0
30-34	1485	414	364	46
35-39	4072	994	760	171
40-44	9202	1843	1393	336
45-49	15407	2659	1788	714
50-54	17534	2965	1741	998
55-59	19690	2913	1576	973
60-64	20700	2536	1484	854
65-69	19000	2250	1285	688
70-74	16115	1776	960	497
75-79	15172	1387	764	355
80-85	12543	1072	513	264
85+	10698	874	360	156

Table F-4. Number of cervical cancers by age and race/ethnicity, United States, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
10-14	0	0	0	0
15-19	0	16	0	0
20-24	81	66	26	0
25-29	326	145	103	0
30-34	597	170	197	21
35-39	952	225	295	72
40-44	999	265	294	51
45-49	1013	218	254	73
50-54	843	198	197	68
55-59	739	161	157	72
60-64	600	135	125	62
65-69	478	112	86	26
70-74	349	94	64	23
75-79	301	63	55	19
80-85	252	60	34	21
85+	219	0	24	0

Table F-5. Number of colorectal cancers by age and race/ethnicity, United States, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
10-14	0	0	0	0
15-19	23	0	0	0
20-24	49	0	0	0
25-29	131	36	26	0
30-34	245	56	51	24
35-39	562	150	120	40
40-44	1213	312	177	67
45-49	2185	582	276	151
50-54	3498	943	452	261
55-59	4220	953	437	281
60-64	4901	888	447	254
65-69	5792	945	475	270
70-74	6504	1015	429	289
75-79	7935	950	504	286
80-85	8240	815	411	233
85+	9799	768	351	208

Table F-6. Number of endometrial cancers by age and race/ethnicity, United States, 2007

Age Group	Race/Ethnicity			
	White	Black	Hispanic	Other
10-14	0	0	0	0
15-19	0	0	0	0
20-24	0	0	0	0
25-29	73	17	55	0
30-34	224	42	92	24
35-39	539	64	151	46
40-44	1010	129	205	96
45-49	2107	219	211	149
50-54	3945	348	311	250
55-59	5401	555	399	236
60-64	5491	683	382	197
65-69	4273	649	294	135
70-74	3276	494	212	92
75-79	2762	352	141	75
80-85	2191	199	98	25
85+	1759	154	57	0

We converted incidence (a rate), to probabilities as described above, and assumed that the pooled odds ratios from the meta-analyses were reasonable estimates of the relative risk. We modeled the conditional probability of dying from each cancer for the first 5 years after diagnosis by using SEER relative survival data, stratified by age group and race. Survival data are stratified only as white versus black, without adjustment for ethnicity. We assumed that survival for Hispanics and non-Hispanic other races was identical to whites, and applied the estimates for blacks to non-Black Hispanics.

We used the number of cases at the start of the followup period and the reported relative survival rates for each year shown in the tables to generate estimates of the number of patients alive and dead at the start of each interval. These numbers were then used to create beta distributions for the annual probability of death, which were subsequently converted to monthly probabilities.

Table F-7. 5-year relative survival by age and race for ovarian cancer

Race and Age	Percent Surviving at End of Interval					
White						
Age	Number at Start of Followup	1 year	2 years	3 years	4 years	5 years
0-44	1106	93.90%	87.80%	83.30%	79.50%	74.40%
45-45	1805	91.00%	80.80%	71.60%	65.00%	59.20%
55-64	2197	86.10%	73.70%	61.70%	52.50%	46.10%
65-74	1829	76.00%	60.90%	50.40%	41.70%	34.00%
75+	2568	1.00%	1.20%	1.30%	1.40%	1.50%
Black						
Age						
0-44	171	50.80%	38.70%	31.60%	25.60%	21.70%
45-45	195	87.20%	77.70%	69.70%	66.30%	62.90%
55-64	207	76.90%	62.80%	52.60%	44.70%	38.60%
65-74	174	67.90%	55.70%	41.20%	38.20%	33.10%
75+	169	40.80%	30.40%	22.20%	15.20%	14.40%

Table F-8. 5-year relative survival by age and race for breast cancer

Race and Age	Percent Surviving at End of Interval					
White						
Age	Number at Start of Followup	1 year	2 years	3 years	4 years	5 years
0-44	11,155	99.00%	96.40%	94.10%	91.90%	89.60%
45-45	21,053	99.00%	97.20%	95.20%	93.60%	92.20%
55-64	21,814	98.30%	96.70%	95.00%	93.40%	91.90%
65-74	16,933	98.10%	96.90%	95.10%	93.40%	92.20%
75+	18,574	0.10%	0.20%	0.30%	0.30%	0.40%
Black						
Age						
0-44	2090	96.40%	94.40%	92.90%	91.90%	90.50%
45-45	2943	96.70%	90.00%	83.90%	79.70%	75.90%
55-64	2476	96.60%	90.20%	85.10%	81.10%	77.90%
65-74	1599	95.50%	91.00%	87.00%	82.60%	79.60%
75+	1411	88.40%	83.80%	80.10%	74.50%	72.30%

Table F-9. 5-year relative survival by age and race for cervical cancer

Race and Age	Percent Surviving at End of Interval					
White						
Age	Number at Start of Follow-up	1 year	2 years	3 years	4 years	5 years
0-44	2,160	95.90%	90.00%	87.00%	85.60%	84.80%
45-45	1,059	88.40%	79.10%	73.70%	70.10%	66.30%
55-64	686	83.10%	71.40%	66.80%	63.90%	61.00%
65-74	456	77.60%	69.50%	61.60%	57.80%	53.30%
75+	378	2.00%	2.30%	2.60%	2.70%	3.00%
Black						
Age						
0-44	369	59.00%	45.50%	41.00%	36.00%	30.30%
45-45	218	90.30%	79.70%	75.70%	74.10%	73.30%
55-64	171	85.70%	75.90%	71.60%	65.30%	60.00%
65-74	105	82.10%	71.00%	67.80%	62.50%	59.40%
75+	94	60.00%	43.90%	42.00%	35.60%	28.70%

Table F-10. 5-year relative survival by age and race for colorectal cancer

Race and Age	Percent Surviving at End of Interval					
White						
Age	Number at Start of Followup	1 year	2 years	3 years	4 years	5 years
0-44	1,384	93.10%	85.60%	79.30%	75.70%	72.50%
45-45	3,150	92.70%	85.80%	80.90%	76.40%	73.70%
55-64	4,574	90.00%	82.40%	77.30%	73.50%	70.40%
65-74	6,334	85.40%	78.80%	74.30%	71.10%	68.90%
75+	13,107	0.50%	0.60%	0.60%	0.70%	0.80%
Black						
Age						
0-44	323	74.90%	68.50%	64.60%	62.70%	61.30%
45-45	764	89.00%	76.20%	69.00%	63.80%	63.20%
55-64	952	88.30%	79.90%	73.60%	68.60%	65.70%
65-74	948	85.00%	74.90%	68.80%	65.10%	61.30%
75+	1246	67.10%	58.50%	52.60%	50.00%	46.80%